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LITERATURE REVIEW: COMPLIANCE/LIFESTYLE CHANGE FACTORS

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Executive summary

This literature review has been conducted within the Connected Health Early Stage Researcher Support System (CHESS) project; under the framework of Marie Skłodowska-Curie grant agreement NO. 676201 to deliver a literature review on compliance/lifestyle change factors for the Work package WP2.

<u>Background:</u> The problem of patient compliance is becoming one of the most alarming in the medical practice worldwide. Studies showed that the low level of compliance is widely spread among patients with various diseases; yet, patients with chronic diseases are in the critical position due to the need to follow recommendation for a longer period of time, and very often - lifelong. Formation of patient compliance depends on many factors, including physician's personality and style of medical practice, organization of health care and availability of certain facilities, particular aspects of a medicinal therapy regimen, socio economic circumstances, personal and psychological characteristics of a patient, etc. However, in most cases, patients with different chronic diseases are considered to be different subjects from the perspective of factors affecting their adherence. Therefore, there is a need for a separate investigation of different groups of patients (e.g., patients with human immunodeficiency virus (HIV), patients with heart disease, etc.). Narrowing, there is limited data on patient adherence to a particular lifestyle change recommendation and its regimens, including maintenance of physical activity and physical fitness, following a balanced diet, etc. Considering physical activity and exercise as an essential part of lifestyle to control heart disease and prevent its further progression, this review focuses on a literature review of the influence factors associated with physical-activity-related adherence modification in a group of patients with heart disease.

<u>Objectives:</u> The objectives of the review include (A) identification of particular types of physical-activity-related behaviour and its settings in regard to adherence in patients with heart disease, (B) assembling adherence measurement criteria, (C) examination and classification of factors affecting adherence, and (D) analysis of adherence change power of specific programs, interventions, and its components based on the selected literature.

<u>Methods</u>: A comprehensive literature review was conducted based on the Arksey and O'Malley methodological framework. The procedure included identification of the literature review scope and research questions, establishment of the criteria for the relevance, study selection, charting the materials, and collating, summarizing, and reporting the results. When it was applicable, the systematic review approach methods were used in order to narrow and increase the quality of the final results. To complete the literature review, sources were accessed between March and August 2016.

<u>Results:</u> Outlined in the review results, a basis and key findings are highlighted for the development of the diagnostic algorithms to predict the adherence to a particular physical-activity-related behaviour of patients with heart disease. Addressed physical-activity-related behaviour is narrowed with regard to lifestyle physical activity and exercise regimen, or physical fitness. The interpretations of the results considered in the review, along with measurement criteria, and context of each of the behaviour, together with provided variety



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of associated factors and their complex relations to physical-activity-related adherence, allow to optimize patient assessment approaches, and as a result intervention strategies, through recommendations and rehabilitation programs tailoring for lifestyle change and adherence modification.



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Chapter 1. Introduction

1.1 Perspectives of patient compliance and lifestyle change

It is a known fact that most of the success in the treatment of diseases largely depends on the quality of medication, its dosage, availability, and accuracy of prescription [1, 2]. However, as it became known in recent decades, the necessity of any treatment process lies under readiness and desire of a patient to comply with medical recommendations [3,4,5].

To refer the accuracy of patient observance with recommendations given by a doctor, the concept «compliance» was proposed. Originally, the term has been defined as "*the extent to which the patient's behavior (in terms of taking medications, following diets, or executing other lifestyle changes) coincides with medical recommendations*" [5]. However, the definition was mainly applied to a medicinal therapy regimen. Later, "compliance" was considered in a simplified form, and described as *«patients doing what health Professionals want them to do»* [6]. Today, this approach is rather limiting the understanding of the "compliance" problem, from both patients' and doctors' perspectives, and bears a shade of paternalism [4].

The ongoing evolution of the "patient - doctor" relation implies a transition of relations between a patient and a health care professional in the direction of partnerships, where the patient takes an active position in the disease management, including following given therapeutic recommendations [7,8]. Due to this reason, increasingly raises a question of appropriate use of the term "compliance", and close to its nature of meaning the term "adherence". Despite the difference in semantics, these concepts are usually interchangeable in the environment of daily medical practice, and are mainly applied to characterize patient's precision of following to a given prescript [9]. Considering the perspective of long-term therapies, the representatives of the World Health Organization (WHO) propose the use of the term "adherence", and define this concept as "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" [10].

The problem of patient adherence is becoming one of the most alarming in medical practice worldwide. According to the WHO experts, poor adherence to therapies and lifestyle change recommendations is a global issue with enormous significance; furthermore, improvement in patient compliance is a health care key strategy [10].

Studies show that the low level of compliance is widely spread among patients with various diseases; yet, patients with chronic diseases are in the critical position due to the need to follow recommendation for a longer period of time, and very often - lifelong. According to the WHO report, the overall long-term adherence in patient with chronic diseases is estimated in no more than 50% of total cases, even considering that many chronic diseases cannot be cured and often, as a progression, provoke pain with persistent negative consequences [10]. The progressive nature of chronic disease leads to increasing pain, limits the execution of the essential daily activities, and requires financial investments [11,12]. In consequence, the patient starts to feel hopeless, irritated, aggressive to family and social interaction, and develops a negative attitude towards the need to seek a medical support. Depressive





condition, along with the feeling of helplessness and absent or insufficient family support, forms a negative mindset to therapy in general, and as a consequence – leads to non-compliance with recommendations [13,14].

Formation of patient compliance depends on many factors, including doctor's personality and style of medical practice, organization of health care and availability of certain facilities, particular aspects of a medicinal therapy regimen, socio - economic circumstances, personal and psychological characteristics of a patient, etc. [10]. Speaking of the latter, personal and psychological patient characteristics (e.g., emotional reaction and health-related behaviour in regard to a given prescription, fears of possible side effects, the level of awareness and understanding of responsibility in the disease self-management, the fact of having anxiety and depression disorders, etc.) acquired a special attention to the research interest in the study of the formation of (non-) compliance and its influence on other health-related behaviour [11,13–17]. Therefore, there is a need for a separate investigation of different groups of patients (e.g., patients with human immunodeficiency virus (HIV), patients with heart disease, etc.). Narrower, there is limited data on patient adherence to a particular lifestyle change recommendations and its regimens, including maintenance of physical activity and physical fitness, following a balanced diet, etc. [10].

Furthermore, influence and associated factors with regard to (non-) adherence in a specific group of patients to a particular regimen of therapy and lifestyle change recommendations, the next section of the review addresses physical-activity-related adherence in patients with heart disease.

1.2 Physical-activity-related adherence in patients with heart disease

The most common chronic illness that characterizes the state of public health and has a notable effect on major global indexes of morbidity, disability and mortality, is cardiovascular disease (CVD) [18]. The disease is caused by disorders of the heart and blood vessels, and includes coronary artery disease, stroke, hypertension, peripheral artery disease, rheumatic heart disease, congenital heart disease, and heart failure [19]. Today, CVD is a leading cause of death throughout the world. According to the global statistics provided by the World Health Organization (WHO) for the year 2012, 17.5 million people died due to cardiovascular disease; of these, 7.4 million died of coronary artery disease [19]. Moreover, since 1990, more people have died from coronary artery disease than from any other cause [21].

The major causes of heart disease, and cardiovascular disease in general, are lifestyle factors and health-related choices, such as tobacco use, physical inactivity, an unhealthy diet and harmful use of alcohol [19]. In this context, patients are not helpless towards their heart condition. According to information provided by WHO, in about 80 - 90% of deaths from coronary artery disease, the critical factors are lifestyle factors [21]. Meaning that, changes in daily life in regard to compliance with therapeutic recommendations to maintain a healthy diet, regular physical activity and exercise, and smoking cessation, patients can make a sustainable contribution to stabilizing the condition, and preserving it from worsening.





Despite the importance of making healthy choices on a daily basis, an overall patient adherence to such changes is extremely low. Thus, according to the results of a conducted meta-analysis, adherence of patients with heart disease to medicinal regimen estimated to be 20 - 58%, and 22 - 51,4% to recommendations on a diet [4]. Studies show that levels of patient adherence to smoking cessation and physical-activity-related regimen in both, lifestyle recommendations and rehabilitation programs are critically poor as well [10,22,23]. In its turn, physical activity and fitness are two of the major components in therapeutic recommendations for patients with heart disease; further, even at an older age, maintenance of a certain level of physical activity can significantly help to prevent disease complications [24].

According to studies in different domains, patients with heart disease do not follow given recommendations for a variety of reasons and multidimensional factors. The main ones are: lack of motivation, low efficiency of treatment, lack of desire to change lifestyle, mistrustful character of relation with a physician, lack of knowledge and awareness about the possible prognosis of the disease and its real possibilities of change, a high level of anxiety and depressive disorders, etc. Two important factors of ignorance or total rejection of therapeutic recommendations are the problem of recurrence of the disease and comorbidity [10,17,23,24]. To conclude, formation process of the disease perception and related adherence to a specific recommendation regimen by a patient is very complex, contradictory and dynamic. The process is determined not only by the environment that a patient lives in, but physiological and psychological characteristics of this patient.

Analysis of factors affecting patient adherence and its modification, enables to design successful actions for adherence improvement, allocate non-adherence risk factors, and make adjustments in the rehabilitation programs and interventions for non-adherence and lifestyle change. In most studies, the main focus of interest is represented by patient adherence to medicinal regimen, and involves an investigation of associated factors with intake of one or another group of medical drugs, assessments of factors affecting medication adherence. Yet, adherence of patients with heart disease to other regimens of rehabilitation therapy or lifestyle recommendation is still remaining for more scientific attention and research [25].

Development of methods that can influence adherence modification is impossible without further investigation and accumulation into knowledge, of research results on formation factors, and factors associated with adherence and non-adherence to a particular therapeutic recommendation [10,25]. Considering physical activity and exercise as an essential part of lifestyle to control heart disease and prevent its further progression, this literature review is focused on the influence factors associated with physical-activity-related adherence in patients with heart disease.

1.3 Objectives

Six objectives were established based on the research interest and the context of the literature review that has been interpreted prior (*see Section 1.1, Perspectives of patient*



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compliance and lifestyle change, and Section 1.2, Physical-activity-related adherence in patients with heart disease). The objectives of the review include:

- Identifying particular types of physical-activity-related behaviour and its settings in regard to adherence in patients with heart disease
- Assembling physical-activity-related adherence measurement criteria by types of physical-activity-related behaviour
- Examining factors influencing physical-activity-related adherence in patients with heart disease
- Classifying types of relations of factors in regard to adherence, patient internal and external characteristics, and environmental context
- Analyzing adherence change power of specific programs, interventions, and its components based on the published literature

1.4 Practical value of the review

Outlined in the literature review, results may serve as a basis for the development of the algorithms to predict the adherence to a particular physical-activity-related behaviour of patients with heart disease.

Addressed physical-activity-related behaviour is narrowed with regard to daily physical activity and exercise regimen, or physical fitness. Considered definitions, measurement criteria, and context of each of the behaviours, together with provided variety of associated factors and their complex relations to physical-activity-related adherence, allow to optimize patient assessment approaches, and as a result intervention strategies, through recommendations and rehabilitation programs tailoring for lifestyle change and adherence modification.





Chapter 2. Methodology

2.1 Methodological framework

This literature review is based on scoping studies approach. To be specific, Arksey and O'Malley methodological framework with developed advances was selected [26,27]. The methodology preference was due to the several reasons. First, post hoc inclusion and exclusion criteria, search strategy, and analysis were considered as essential methods in conducting relevant articles based on the increasing familiarity with the literature and its heterogeneous nature. Second, both, qualitative and quantitative research designs of the studied literature were considered as important in regard to the established review objectives (*see Section 1.3, Objectives of the research*). Third, concerning the review objectives further, such procedures as examining extent, range and nature of published results, summarizing and overviewing research findings, and identifying research gaps in the existing literature, rather than purely synthesizing published results, were predetermined as necessary. When it was applicable, the systematic review approach methods were used in order to narrow and increase the quality of evidence (e.g., well-established search strategy for databases).

The methodology part of the conducted literature review is described through the five stages (i.e., identifying the research questions, identifying the relevant studies, study selection, charting the data, and collating, summarizing, and reporting results), as discussed below.

2.2 Research questions

The aim of the literature review is to comprehensively examine published literature addressing factors associated with physical-activity-related adherence change in a group of patients with heart disease. To attend the aim and aforementioned literature review objectives (*see Section 1.3, Objectives*), five literature review research questions were established, and classified by the subjects (i.e., physical-activity-related behaviour and adherence, and adherence change factors) for further exploration based on the studied literature. The guiding questions for the literature review are presented in the table below (*see Table 1, Research questions*).

Table 1. Research questions

Subject (s)

Questions to address

Physical-activity-related
behaviour and adherence>What are the types of physical-activity-related
behaviour and its settings in regard to adherence in
patients with heart disease being addressed in the
studied literature?

How are these types of physical-activity-related behaviour defined and measured?





	What are the factors influencing physical-activity- related adherence in patients with heart disease being addressed in the studied literature?
Adherence change factors	How do these factors related to (non-) adherence and how can these relations be classified with regard to patient external and internal characteristics, and environmental context?
	What are specific programs, interventions, and their components addressed in the studied literature; and what is the change power of the mentioned programs in regard to physical-activity-related adherence in patients with heart disease?

2.3 Search methods

To identify relevant studies, eligibility criteria (i.e. inclusion and exclusion criteria) and sources for the research evidence (i.e. scientific databases) were established in prior. Further, advanced search strategy for selected databases was developed based on the systematic review approach. To extend the literature review result, reference lists and results of manual investigation conducted between March and August 2016, were added.

Databases

Two scientific databases, MEDLINE (through the PubMed search engine) and the Cochrane Library, were conducted with the last search updated on 5th August 2016.

Eligibility criteria

The following inclusion and exclusion criteria were used to guide the search strategy (*see Table 2, Inclusion and exclusion criteria*).

Table 2. Inclusion and exclusion criteria

	Published in English language
	 Availability with fully included text
	 Research that targets population with heart disease
Inclusion criteria	Research investigating influence of factors on physical-activity-related adherence
	Studies with the following design: randomized controlled trial, crossover design, cohort study, pilot study, experimental study, case-control study, cross- sectional study, cross-sectional survey



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	Research investigating effect related behaviour on other contextual factors		2
Exclusion criteria	Research investigating effect of on other patient-related and where physical-activity-re impossible to separate	d contextu	al factors,
	Review articles, guidelines, paper, and protocols	lectures,	conference

Search strategy

To conduct database search, three main search concepts were defined based on the research interest and the context of the literature review; these are: (A) influence factors, (B) adherence to physical-activity-related behaviour, and (C) heart disease. In regard to these concepts, keywords (i.e. terms and synonyms) were specified and applied for further search strategy development (*see Table 3, Search concepts and keywords*).

Concept A		Concept B	Concept C	
Influen	ce factors	Adherence to physical- activity-related behaviour	Heart disease	
 Predict Associate 	 Factors Barriers Risk factors Determinants Correlates Predictor (s) Relationship (s) Association 	 Adherence Patient Physical activity Exercise Compliance Physical fitness 	 Heart disease Heart failure Coronary artery disease Cardiac rehabilitation Heart rehabilitation 	

Table 3. Search concepts and keywords

For both databases, advanced searches using Boolean operators (i.e., "AND", "OR", "near"), and Medical Terms (MeSH) (i.e. "Patient compliance", "Compliance", "Motor activity", "Exercise", "Physical fitness", "Heart failure", "Heart diseases", "Coronary artery disease", "Heart", "Rehabilitation") were applied. To filter the results, library tools were used in both of the databases: "[Title/Abstract]" search in the PubMed, and Cochrane Review Group (i.e. "Heart group") in the Cochrane Library. Each database was assessed twice with Preliminary and using MeSH search strategy (*see Appendix 1*, Databases search strategies). In summary,



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four searches within two databases were conducted in order to extend the results with potentially relevant literature.

2.4 Literature selection

The selection process was performed in two steps. First, title and abstract were screened to determine eligibility of an article based on the inclusion and exclusion criteria. Then, if the article was considered as a potentially relevant candidate, the full text was accessed. Papers with no proven results related to the investigating factors (e.g., authors' suggestions) were excluded. Relevant duplicated articles were included in the final results once. To minimize the risk of disregarding relevant or including irrelevant literature to the final results, the selection process was iterated.

Within four conducted database searches, randomized controlled trials were screened first due to their high evidence-based nature. The results of papers with main focus on interventions and their effectiveness were screened and classified for the further separate analysis of the results. It was done due to clarification and description of settings and effects of a precise intervention on a particular subgroup of patients with heart disease.

Out of original 277 yielded publications, 58 were included for further analysis (*see Figure 1, Literature selection results from databases*). With respect to the additionally performed manual search, 5 relevant papers were added to the final results.

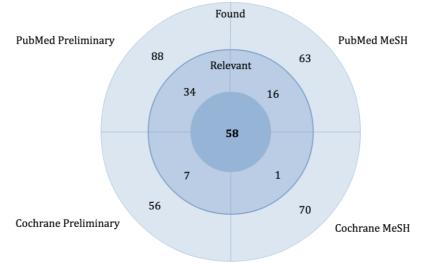


Figure 1. Literature selection results from databases

2.5 Data extraction and analysis

To proceed with selected articles, a data-charting framework was developed as a basis for further classification and analysis of the results. The framework is built upon five major aspects, in order to represent the data from each of the relevant articles, including primary study information, study population characteristics, specifications of physical-activity-related adherence and factors, and supplementary information (i.e. limitations). The table listed below describes viewpoints of the aspects (*see Table 4, Data extraction framework*).





Table 4. Data extraction framework

Aspect (s)	Description
Study	 Author (s), title and year of publication Study location Study objectives Study design Study duration Number of participants
Study population	 Specifics of participants (e.g., heart disease, gender, age, ethnicity) in study group
Adherence to physical-activity-related behaviour	 Type of physical-activity-related behaviour Given definition Measurement criteria Settings (e.g., on-site controlled environment such as hospital or specialized sport center, off-site environment such as home)
Factor (s)	 Studied factor or/and combination of factors Specific settings (if applicable) Results, character of impact on adherence
Supplementary information	Study limitations

As a following step, the charted data was interpreted through the instrumentality of descriptive numerical summary and qualitative thematic analysis, and reported referring to the literature review research questions (*see Chapter 3, Results*). Additionally, gaps in the published research targeting physical-activity-related adherence in patients with heart disease were identified and documented, as well as areas where more in-depth analysis is required.





Chapter 3. Results

3.1 Physical-activity-related behaviour: types, settings, and measurement criteria

Patient adherence is an indicator of the performed level of physical activity in everyday life, as well as during cardiac rehabilitation. For a clearer understanding of the concept of (non-) adherence, first of all, attention was paid to the perspectives from which the term was considered in the selected studies. Further, in regard to adherence, the types and settings of physical-activity-related behaviour were determined and classified. Finally, the instruments used up to date to measure the adherence in patients with heart disease were overviewed and briefly described under the present section of the review.

Types and settings

The analysis of the selected intervention studies, mainly allows dividing the concept of physical-activity-related behaviour in the direction of exercise and everyday physical activity. Expanding the understanding and settings for each of the directions, an *exercise* is considered as an activity to improve health condition and physical fitness of a patient [28,30,32–34,36–75]. While *everyday physical activity* represents an activity that a patient does on a daily basis due to the lifestyle, work occupation, etc. [31,40,42,44,45,70,77,86,87]. For example, grocery shopping or walking with a dog will refer to a daily physical activity.

As it follows from the data analysis, exercise may be designated as an independent and controlled activity depending on the site settings (e.g., home-based or off-site, hospital-based or on-site, etc.). If the activity is performed outside of the hospital or other health care facility, and a patient has no real-time supervision of the health care professional (e.g. telemedicine solutions), the exercise can be classified as an *independent* [20,31–34,38–40,44–50,53,55,57–60,62,63,65,66,68,70,71,74,81–84]. Exercise activity performed under supervision in an organized facility, should be classified as *controlled exercise* [28, 36,37,41–43,51,52,54,56,61,64,67,69,72,73,75,76,78–80,85].

In the majority of studies the definitions of a specific physical-activity-related behaviour were not specifically established, except for one, where the independent exercise was defined as "*intentional activity such as walking, cycling, or stair climbing, undertaken for the purpose of increasing health and fitness*" [30]. In other studies, independent exercising is considered as structured training at home or exercising in leisure, including playing exercise games [29]. Everyday physical activity was designated as walking, occupational physical activity, leisure and locomotion activities, or body movements made within the day. The diagram below gives an overview of the studied types and settings of physical-activity-related behaviour).





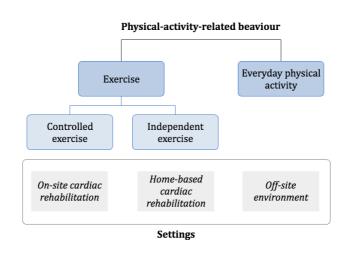


Figure 2. Types and settings of physical-activity-related behaviour

Adherence measurement criteria and dimensions

Nowadays, despite the existing technical and ethical issues and high cost, one of the emerging trends in assessing patient physical-activity-related adherence is the use of technological solutions [88]. Using telemedicine resources, gathering the data on the number of daily steps done, calories burned and heart rate levels change provides an objective evaluation of patients' adherence. However, as shown by the investigation of selected studies, mostly adherence is measured by the data from verbal or written assessments. Only a few studies among all the selected were based on the data from the electronic devices.

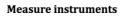
Thus, such subjective method as the interview comes to the fore of the adherence measurement criteria. The advantages of this method are its simplicity and availability. Typically, during the conversation built upon the respect of the patient's point of view and sympathetic attitude of the interviewer, it is possible to get necessary information. As another similar method for measuring adherence, self-reported patient records (i.e. physical activity diaries) were used in all the reviewed for the recent review studies. Keeping a diary with a description of the process of engagement in physical activity helps to analyze patient's adherence, and to determine the factors associated with positive or adverse events in the formation of (non-) adherence. However, the fact that most of the questions in the interviews, assessments and self-reported diaries are very limited in terms of the content and quantity should be taken into account. It is also worth noting that for the data collection, patient-related factors (e.g., patient's memory condition, the desire to "please" recommended requirement, etc.) could seriously limit and complicate the processes of adherence analysis and its results.

Each of the discussed methods (i.e., use of electronic devices, interviews and self-reported assessments) has its own use disadvantages, including high cost, insufficient reliability and a high level of subjectivity. All of these methods characterize patient adherence to physical activity from one narrow perspective, and do not consider the wide variety of possible deviations from the prescribed regimen. This means that the issues of adherence measurement criteria are still open.



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In all examined studies, adherence and/or its level were considered through measurements of physical-activity-related behaviour that have been discussed earlier. More specifically, the adherence has been evaluated through attendance rates of controlled exercise, logs on frequency, amount, persistence and intensity of independent exercise; and through body movements and logs of everyday physical activity. The diagram below provides a graphical overview of adherence measurement instruments and dimensions that have been used in the review studies, and supported further by the brief description of each of the instrument (*see Figure 3, Adherence measurement instruments and dimensions*).



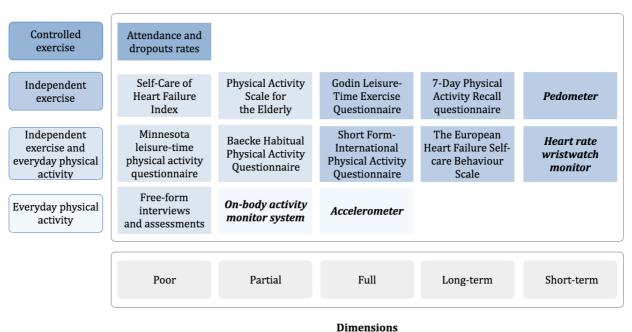


Figure 3. Adherence measurement instruments and dimensions

Attendance and "dropouts" rates: Exercises that have to be performed in a controlled environment (i.e. hospital, specialized sports center, or other health care facility) and belonged to the cardiac rehabilitation program were obtained by collecting rates of sessions' attendance. Based on the rates, adherence was measured in percentage of attendant sessions from the total number of appointed exercise sessions. If the number of attended exercise sessions reached 67% [36,43,54], and more - 75% [64] and 78% [37], the patient was considered as adherent to exercise activity. The measurement criteria for the poor level of controlled exercise adherence were determined by attendance of exercise sessions in 50% of the total amount of session, or less [37]. Authors of several studies did not specify the required percentage or necessary number of sessions that the participants had to attend [28,33,41,51,52,56,61,67,69,72,73,75,76,79,85]. In these cases, (non-) adherence was measured by comparison of participants in different study groups. Failure to attend cardiac rehabilitation program with attendance rate less than 33% [36,54,73], 60% [53], or the complete patient's refusal to attend the program [43,69,78,80] was indicated as a «*dropout*».

<u>Free-form assessments measurements:</u> As it has been mentioned above, in the majority of the selected studies, self-reported physical-activity-related measurements instruments



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were used in a free form based on the defined in the studies precise physical activity behaviour [30,32,34,38,50,58–60,63,66,70,74,77,81–83,87]. Generally, an independent exercise and everyday physical activity levels were assessed by self-reported diaries, questionnaires, assessments and interviews. Patient adherence was measured by minutes of performed physical activity, and the type and intensity of the activity. In several studies, the independent exercise behaviour was defined by the level of adherence, such as poor, partial or full, and was based on the frequency, persistence, the amount and intensity of the performed exercise [58,59]. Despite the simplicity of the assessments, in some studies questions addressed to the physical activity level determination, were part of the multibehavioural assessments, including diet, medication and other lifestyle habits [38,50].

<u>Godin Leisure-Time Questionnaire (LTEQ):</u> Another instrument to measure an independent exercise was the Godin Leisure-Time Exercise Questionnaire [39,49,62,68,84]. A total LTEQ score was calculated by adding the frequency of exercise within the mild, moderate, and strenuous (or vigorous) physical activity. A higher score indicated greater health benefits from the physical activity. In one of the studies, a modified LTEQ version was used, and participants were asked only about mild and moderate intensity leisure time exercise through the following question: "Over the past month, consider a typical week (7 days): How many times on the average did you do the following kind of exercise for more than 15 minutes during your free time?" [68]. An example description of mild and moderate activity (e.g. fast walking) was provided. The modification of the questionnaire was used in other studies as well, with the variation of an exercise time from 10 to 20 minutes [39,49,62].

<u>7-Day Physical Activity Recall (PAR) questionnaire</u>: In two studies, for the patients' independent exercise and everyday physical activity levels measure, the PAR measurement instrument was used [55,57]. Through the interview, participants were assessed about the time spent engaged in moderate, "hard", and "very hard" physical activity for the previous week. Time spent engaged in light activity was obtained by subtracting the average daily time spent in moderate, hard, and very hard activity and sleeping from 24 hours. In one of the studies, a modified version of the questionnaire was applied [55]. From the physical activity estimation, an estimated caloric expenditure was calculated and used for the comparison of the patients.

Minnesota leisure-time physical activity (LTPA) questionnaire: To estimate everyday physical activity and independent exercise activity level during the cardiac rehabilitation program, a modified version of the LTPA questionnaire was used [42]. Physical activities in the questionnaire was grouped (i.e., «walking and miscellaneous», and «conditioning exercise») and assessed through the interview. Participants had to answer about the activities they performed and did not perform within the last 12 months.

<u>The Self-Care of Heart Failure Index (SCHFI)</u>: As well, the SCHFI questions (version 6.2) allowed to address an independent exercise and everyday activity levels. Patients were asked about regularly performed physical activity over the passed month by two questions: "How routinely do you do some physical activity?" and [17] How routinely do you exercise for 30 min?" [40].



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Short Form-International Physical Activity Questionnaire (s-IPAQ): The seven-item questionnaire regarding an independent exercise was focused on the frequency and duration of "light", moderate, and vigorous physical activity, as well as inactivity, during the past week [71]. The four following physical activity types were assessed: "vigorous activity" (for periods of at least 10 minutes), "moderate activity" (for periods of at least 10 minutes), "walking" (for periods of at least 10 minutes), and "sitting". The total physical activity score was calculated as the sum of vigorous, moderate, and walking physical activity scores, and transformed into metabolic equivalent (MET). Then the patients were classified into categories with low, moderate, or high physical activity.

<u>The European Heart Failure Self-care Behaviour Scale</u>: Only one question in the European Heart Failure Self-care Behaviour Scale was addressed to the regularity of an independent exercise, with "yes" or "no" patients' answers [48].

<u>Physical Activity Scale for the Elderly (PASE)</u>: One of the questionnaires to measure levels of physical activity was specifically developed for participants aged 65 years or older [44,65]. In The 10-item questionnaire, the participants were asked for how many days per week, and how much time was spent for sitting, walking, moderate or vigorous activity over the past week. A higher PASE score indicated greater level of everyday physical activity and independent exercise.

<u>Baecke Habitual Physical Activity Questionnaire (Baecke-HPA)</u>: Physical activity addressing such behaviour as occupational physical activity, physical exercises in leisure, and leisure and locomotion activities was obtained by the Baecke-HPA questionnaire. Ranging from "never" up to "always", answers on 16 questions addressing listed behaviour was scored by Laker scale (from 1 to 5) [31]. The higher scores indicated higher levels of physical activity; the range varied from "inactive" (score=3) to "very active" (score=15).

Accelerometer, on-body activity monitor system, pedometer, and heart rate wristwatch monitor: Out of all selected studies, electronic devices, representing objective measurements instruments were used in five [29,32,46,53,86]. An independent exercise and everyday activity levels were measured by accelerometer [29,86], on-body activity monitor system [32], pedometer [46], and a heart rate wristwatch monitor [53].

3.2 Factors associated with physical-activity-related adherence

Patient adherence to physical-activity-related behaviour reflects a complex interaction of different factors, the configuration of which changes not only in the dynamics of the heart disease, but also depending on the specific life circumstances. These factors might be associated with patient personal characteristics, social environment, settings of therapeutic regimen, etc. However, there is no universal classification found to be applied to the factors. Therefore, in the review, adherence-related variables have been classified by eight groups in regard to the nature of its origin. The groups are represented by demographics, socio-environmental, anthropometrical, clinical, health care-service-related, cognitive and psychological, physiological and physical-activity-related, and lifestyle patient data. The



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table further includes a descriptive part for each of the group of classification used for the variables analysis in the selected for the review studies (*see Table 5, Classification of factors*).

Table 5. Classification of factors

Group of factors	Classification of included factors		
Demographical	 Age (i.e., younger, older adults) Gender Ethnicity (i.e., Asian, African American, Black) Marital status (i.e., single, married, divorced or separated, widowhood) Education level Household income (i.e. level of income) 		
Socio-environmental	 Social support (i.e., role and level of family support, encouragement from others, support from people with the same disease) Family-related (i.e., having grandchildren, family responsibilities, home stress) Employment-related (i.e., work status, working hours, conflicts, occupation) Residence and wealth-related (i.e., place of residence, availability of transportation, weather issues) 		
Anthropometric	 Boby mass index (i.e., overweight, obesity, higher or lower BMI) Body fat percentage (i.e. sum of three skinfolds) 		
Clinical	 Health status (i.e., health status, illness severity, physical health) Comorbidity (i.e., diabetes, cancer, musculoskeletal issues, myocardial infarction) Cardiac-related (i.e., angina, cough, angioplasty, readmission) Laboratory results (i.e., cholesterol, triglycerides, high-density lipoprotein) Medication (i.e., use of antidepressant medication) 		





Health care service- related	 Cardiac rehabilitation (i.e., referral, availability of services, support from staff, miscommunication) Insurance (i.e. insurance issues)
Cognitive and psychological	 Mental health Disorder (i.e., anxiety, depression, neuroticism, mood disorder) Perception (i.e., perceived health, perceived susceptibility, perceived benefits and barriers, perceived health beliefs, perceived self-efficacy, fears, life goals, stages of change) Motivation Action planning (i.e., action planning, intention)
	 Knowledge
Physiological and physical-activity- related	 Physiological state (i.e. fatigue, suffering from minor injuries) Work capacity (i.e., baseline work capacity, exercise capacity, peak heart rate, peak oxygen uptake, peak blood pressure) Experience
Lifestyle	 Lifestyle habits (e.g. smoking)

In each of the groups, there are factors facilitating the formation of patient adherence or nonadherence. While the process of the studies examination, it was noted that combination of the factors that determine adherence might strengthen or weaken the effect of each other, as well as patient adherence in general (*see Appendix 2–10, Factors associated with physicalactivity-related adherence*). The identified statistically significant factors, and their influence on patient adherence to physical-activity-related behaviour are discussed further.

Demographic factors

Demographic factors such as, age, gender, ethnicity, education and household income, are the most reliable and available for investigation, and as they were concluded based on the selected studies, with a strong prognostic power in the domain of physical-activity-related behaviour (*see Appendix 2, Demographic factors associated with physical-activity-related adherence*). Despite the fact that the studies are mainly were organized with the older adult population, the *age* itself was positively correlated with physical-activity-related adherence [37]. In support, older age was positively associated with adherence formation as well [72]. At the same time, patients with younger age generally had poor adherence [58], and more



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likely were prone to dropouts [36,57]. However, there is a disagreement in the literature regarding the influence of the age factor; in one study, younger age was positively associated with adherence as well [44].

Despite the fact that the predominant study population of the studies was men, *male sex* has been positively associated with adherence [44,73]. In contrast, *women* were associated with poor adherence [58,74,87], and even dropouts [57]. Only in one study, *male sex* was a predictor of rehabilitation program dropouts as well [80].

The obtained data on the dependence of patient adherence by the ethnic factor showed, that Black people were less adherent [58,72] and more likely to withdraw from the exercise regimen of cardiac rehabilitation [57]. Considering the three mentioned factors (i.e., age, gender and ethnicity) in combination, there are significant results that **younger woman** [56] and **Asian woman** [51] are less compliant with recommendations, while the **older women** had higher levels of physical activity adherence [56] (*see Appendix 10, Combination of factors associated with physical-activity-related adherence*).

One of the most unambiguous factors was a marital status. Patients who were *married* or in a relationship, showed higher adherence to physical activity [29,44], while *single* or *not married* [64,73], *divorced or separated* [33], and *widowed* [67] were less likely to exercise but more likely to withdraw from rehabilitation programs.

Also, it is interesting to note that the *lower level of education* [29,42] and the *higher household income* [44,45,72], both had a positive association with adherence formation. In contract, *financial issues* impeded everyday physical activity [77].

Socio-environmental factors

As set forth above, patients who were married and had a family, had higher levels of physicalactivity-related adherence, compared to patients in other marital statuses. The presence of beloved ones, and its associated *social support*, appeared to be influencing factors on the everyday physical activity, as well as exercising [46,70]. For example, a *high level of social support* showed to be influencing factor for more active patients' life from perspective of physical activity [44,48,55,77], whereas *poor social support* [58,80] and *lack of encouragement from others* [59] lead to decreased time spent on exercise, its poorer adherence and dropouts. Furthermore, as has been found, according to the results of one of the studies, *having grandchildren* positively influenced the frequency of exercise in leisure [29]. However, the presence of family and relatives could negatively affect the patient's physical activity level. *Presence of home stress* [56], and large number of *family responsibilities* [71] proved to be barriers to exercising or participating in rehabilitation programs.

The results of the studies have shown that *being employed* significantly affected the formation of the (non-) compliance [73]. Thus, working patients were more prone to withdraw from rehabilitation programs for the reasons of *time conflicts, full-time work status*, and *work conflicts* [44,52,54,56,57,71,77]. Additionally, *blue-collar occupation* itself showed to increase the chances of patient dropout from the exercise regimen of



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rehabilitation program [36]. However, the status of *being not employed* also showed its predictive power in dropouts [78].

The factors related to the patient's residence can also affect physical-activity-related behaviour. Thus, the *weather issues* [59,65,77] and a *transportation difficulties* along with *living outside of the city* [56,65,73] may seriously decrease attendance of rehabilitation programs, while the fact of *having own transport* showed to neutralize the effect of the mentioned barriers [44,78].

Anthropometric factors

Studied anthropometric factors, mainly included two variables – body mass index (BMI), and body fat percentage (the sum of the triceps, subscapular, and suprailiac skinfolds) (*see Appendix 4, Anthropometric factors associated with physical-activity-related adherence*). Generally speaking, **BMI** and the **sum of three skinfolds** were patient adherence predictors with a negative correlation [37]. In the examined studies, higher BMI, and related **overweight** and **obesity**, were mainly associated with poor [69] and non-adherence [43], and early dropouts [64] and dropouts in general [57]. However, in one of the studies, **lower BMI** was also associated with poor adherence [53], which raises concerns and requires further investigation.

Clinical factors

In the literature review, clinical factor included variables related to patient health status, presence of comorbidity, cardiac-related issues, and laboratory test results and taken medication (*see Appendix 6, Clinical factors associated with physical-activity-related adherence*). The strongest predictor of poor adherence and withdrawal from cardiac rehabilitation programs was the fact of having *comorbidity* [46,52,53,59]. *Diabetes* [43,69,74], *cancer* [74], *musculoskeletal issues* [60,73], and *medical problems* [54,73], and a history of *longer heart failure duration* [53] were associated with poor adherence or not following the recommendation and rehabilitation program at all. Moreover, patients with *diabetes* were more likely to withdraw from the rehabilitation program in the early stages [67]. Patients who were taking antidepressant medication were inclined to withdraw from rehabilitation at the early stage as well [64]. *Muskoloskeletal issues* were represented as one of the strongest barriers due to the patient's discomfort and presence of pain while performing an exercise [73].

Patients with accompanying factors associated with heart disease, such as *readmission* [64], *angina* [36], and *presence of cough* [36], were classified in a group of patients with a high probability of dropout; although patient with history of *myocardial infarction* [73,78] or *heart failure* [87], and undergone *angioplasty* [73] have been classified as patients with high barriers to rehabilitation participation and completion, as well as to exercising in leisure. Overall, patients with higher *illness severity* [40,76], the higher score of *health status* [63] and *fewer comorbidities* [44,47], were more compliant with therapeutic recommendations.



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The study of patient adherence and accompanying laboratory results showed that an increase in *triglycerides* indexes [37] and *total cholesterol* [37] was indicating the level of patient adherence, while growth in *high-density lipoprotein cholesterol* indexes was correlated with an increase in physical activity [37]. *Cholesterol control* was associated with a positive effect on adherence modification [44].

Health care-service-related factors

The organization of health care services plays an important role in regard to patient adherence formation, which was addressed in the examined studies. Based on the analyzed literature, it can be drawn that the variables related to cardiac rehabilitation settings, such as fact of *referral to the rehabilitation* [74] and further *post-discharge cardiac visits* [74], had a positive association with adherence to physical exercise (*see Appendix 7, Health careservice-related factors associated with physical-activity-related adherence*). In turn, regular cardiac visits might depend on the availability of health care facilities; *availability issues* [65] and *suitability issues* [78] were found as a barrier to patient adherence formation.

Equally important is the relation "patient – doctor". A higher level of *health care staff support* [44], *physician's recommendation* [78], and *e-mail or phone notifications* [78] about recommended activity were defined through positive association with physical activity adherence [44], while *miscommunication* [70,73], *lack of specific recommendations* [70], and *lack of physician referral* [52] have been identified as barriers. Results of one of the studies showed that *physician's recommendation* was a predictor of rehabilitation program entry [76].

In one study, the impact of health care insurance was discussed, and it was found that the presence of *insurance issues* could contribute in prediction of exercise program dropouts [54].

Cognitive and psychological factors

Often, patients with heart disease have not only physiological comorbidities, but also problems in psycho – emotional domain. For this reason, cognitive and psychological factors take an important place in the process of adherence formation, and have been addressed in most of the investigated studies (*see Appendix 8, Cognitive and psychological factors associated with physical-activity-related adherence*).

Depression and anxiety disorders particularly affect pathogenesis of many somatic disorders in patients with heart diseases, and significantly complicate the formation of physical-activity-related adherence. In the analysis of studies, a higher patient's score for *depression* and *anxiety* signalized about the lower level of adherence to physical exercise [33,37,76,80]. The fact of the presence of *depression, anxiety* or *mood disorder*, indicated poor adherence and was an adherence predictor in general [54,61,73]. Considering *ill perception* [81] and *mental health* [47] overall, it can play a role of predictor of patient adherence to physical activity in different settings.

The level of patient (non-) adherence is closely linked to the patient's characteristics and



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perception, as well as mood. For instance, the stronger *threat to self-concept* [38] or the *higher perceived health* [44], the lower physical activity adherence. At the same time, *negative perception of heath* and *low mood* were considered as a barriers to the daily physical activity [77]. In the studies, patients with poor adherence were associated with *lower self-efficacy* [57] and *high barriers* [58] to exercise and adherence in general. At the same time, *higher self-efficacy* [49,63,71], *self-efficacy* [40,84,87], and *recovery self-efficacy* [50] gave a positive association, correlation and prediction of the exercise performing. Overall, self-efficacy can be seen as a variable with a strong predictive power [55,62].

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Motivation [71] and existing *knowledge* about the disease [75] have been positively associated and correlated with patient adherence [71,75,87]. *Motivation* also was a predictor of independent exercise [83,83]. In turn, the *lack of motivation* [47,77,78] and *lack of knowledge* [87] has been established as a barrier in the process of adherence formation. The *lack of interest* in performing a physical exercise [73] was also considered as a barrier, and in order for a patient to stay adherent, an importance was given to the factor of *physical activity enjoyment* [44].

In this case, the value has been given to a certain *life goals and interests* [40,41,77] and *irrational health beliefs* [72], which showed to influence the adherence. For example, a patient could be inspired to have the beneficial level of physical activity and exercise in order to keep a physical shape for the possibility to travel or spend more active time with a family [41]. In another study, *perceived benefits* of exercise have also been positioned as a predictor and facilitator of the patient adherence [42,55,77].

In the selected studies, the process of *action planning* [50], *intention* [50,62], and being classified with one of the *stages of change* [55], has been given with a predictive power which allow to prognoses the adherence to physical activity regimen. *Goal settings* showed its motive power to patient adherence [77], while analysis of the studies let to determine the *perception of control* [68,81] and *susceptibility* [42] as the factors playing an important role in performing exercise and physical activity in general.

Often patient's mindset is closely related to the chosen expectations and actions. Thus, *ill-health avoidance* variable showed its facilitating power to patient adherence, which means that some patients could be motivated to the exercise due to the fear of disease circumstances [41]. Oppositely, *fears about cardiac circumstances of exercise* [70,71,77], *perceived barriers to exercise* [55], and *lack of perceived benefits* [59] were found as behaviour affected in regard to comply with recommendations; as well as the *lack of the interest* [54] and the process of *experiencing a personal stressful event* during exercise [78] signified about patient dropout from the supervised exercise program.

Physiological and physical-activity-related factors

Physiological and physical-activity-related factors included physiological state, work capacity and the level of patient exercise experience (*see Appendix 9, Physiological and physical-activity-related factors associated with physical-activity-related adherence*). Several studies have shown that issues related to patient physiological state, such as **presence of**



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minor injuries [71], *physical symptoms* [47,59], *physical restrictions* [77], and *fatigue* [47,71,78] could be considered as a barrier to performing the exercise activity. *Lack of exercise experience*, which could lead a patient to an uncomfortable feeling from the psychological and physiological point of view while performing the exercise, has been reported as an adherence barrier as well [71]. *Initial exercise capacity* (or baseline exercise capacity) was found as a common predictor [37,68], and its *low level* – a predictor of an early dropout [67].

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Assessing adherence in patients with heart disease, the result of the *peak heart rate* measure [37], the *exercise test* [37], and *higher oxygen uptake peak* [44] should be taken into account due to its positive association and correlation relation with patient adherence. Additionally, the results of the vital measures showing *higher resting systolic* [36] or *lower diastolic blood pressure* [69] could benefit to the understanding of heart disease patients' poor adherence or dropout.

Lifestyle factors

Among examined lifestyle factors (i.e., alcohol consumption and smoking) only *smoking* habit was defined as an influence factor on physical activity adherence (*see Appendix 5, Lifestyle factors associated with physical-activity-related adherence*). Specifically, smoking has been associated with poor adherence [37,56] and was a predictor of early dropouts [67] and dropouts in general [36]. Therefore, the habit could be considered as a variable with a strong predictive power.

3.3 Compliance change power of specific intervention programs and interventions

One of the methods to change patients' compliance or adherence to a desirable behaviour is to apply an intervention program or an intervention [10]. Based on the selected literature, studies that examined possible effects of the proposed intervention programs for patients with heart disease were analyzed [28,29,30,31,32,33,34]. Particular attention has been given to such directions in the studies as (A) study population, (B) intervention program design, (C) outcomes, and (D) limitations.

The total number of studies examining the effect of the developed interventions amounted to seven. Despite the narrow number of studies, the majority of them were held in the Nordic countries (two studies were carried out in Norway [28,32], and one in Sweden [29]), and in the United States (three studies as well [30,33,34]). One study was conducted in Brazil [31].

The main objective of the majority of studies that have been conducted in a relation to verify the intervention effect was increasing and maintaining levels of physical activity in patients with proven heart disease [28,29,30,31,32]. However, in two studies, the objectives were to ascertain variables predicted adherence to a precise physical-activity-related behaviour within a particular intervention program [33,34].





A. Study population

Considering inclusion criteria for study population across the selected literature, all the claimed diseases are of chronic cardiac pathology. Predominant disease in the studied patients groups was coronary heart disease (or coronary artery disease) and its sequels (i.e., angina, myocardial infarction, etc.) [28,30,31,32,33,34]. However, intervention studies are highly heterogeneous with regard to the studied population. The primary cause is a dominance of certain patient-related variables. The table further presents an overview of the studied patients' groups, and the dominating variables in these groups (*see Table 6, Dominating patient-related variables in the selected intervention studies*).

Among the population in six studies, the dominating gender was male [28,30,31,32,34]. Only one study was gender-oriented, and the study population consisted of female patients [33]. The predominant age of the patients was of an older adults patient group [35]. In four out of seven studies, the majority of patients were married or in a relationship [28,29,31,34]. Similarly, in four studies, population was dominated by obese patients [29,30,31,34], and patients with a history of a heart failure [28,30,31,33].

Specified in the studies, patient-related variables can be assigned to demographics (age, gender, ethnicity), socio-environmental (marital status, family-related data, work occupation) and lifestyle (smoking, alcohol consumption), anthropometric measurements (body mass index, BMI), and clinical data (comorbidity). Variables related to the psychological aspects of the study population (i.e., self-efficacy, anxiety, and social support) from the perspective of influence on the adherence, were addressed in two of the analyzed intervention studies [33,34].

Table 6. Dominating patient-related variables in the selected intervention studies

Dominating patient-related variables

The Vestfold Heartcare StudyGroup. (2003) [28]

- A. Diagnosed with coronary heart disease
- ➢ Mean age − 55 y.o.
- ➤ Male 82%
- Married 84.77%
- After major coronary event 84,77%
- Acute myocardial infarction 70%

Klompstra, L., Jaarsma, T., & Strömberg, A. (2014) [29]

- A. Symptomatic heart failure class II-IV (New York Heart Association)
- Mean age 63 y.o.
- ➤ Male 69%
- Level of education higher than a high school - 57%
- Married or in a relationship 90%
- Having children 97%





- ➢ Having grandchildren − 82%
- Non-smokers 96%
- Low alcohol consumption (glass of wine or less a week)– 52%
- ➢ Obesity 78% (BMI > 25)

Barkley, S. A., & Fahrenwald, N. L. (2013) [30]

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- A. Diagnosed with coronary artery bypass graft, myocardial infarction, percutaneous coronary intervention, heart failure, or stable angina
- B. Participation in cardiac rehabilitation programm, II phase
- Mean age 66 y.o.
- ➤ Male 64%
- ➢ Obesity (mean BMI = 28,78)
- Acute myocardial infarction or coronary angina – 65,6%

Cunha, R., Rodrigues, M., Cecília, M., Jayme, B., Maria, N., & Alexandre, C. (2013) [31]

- A. Diagnosed with coronary heart disease
- B. Low level of education and income

Mean age – 59 y.o. ≻ Male - 63% \geq \triangleright Caucasian - 82.35% ≻ In a relationship/with companion – 71% \triangleright Not employed (professionally inactive) -80,9% \geq Obesity (mean BMI = 27,9) \triangleright Acute myocardial infarction – 65,6% \geq Coronary angina within last month – 58,9% \geq Hypertension - 76,4% \triangleright Dyslipidemia – 76,4%

Madssen, E., Arbo, I., Granøien, I., Walderhaug, L., & Moholdt, T. (2014) [32]

- A. Diagnosed with coronary heart disease
- B. Previously completed 12-week cardiac rehabilitation program in a hospital

Beckie, T. M., & Beckstead, J. W. (2011) [33]

- A. Diagnosed with acute myocardial infarction, angina, or having undergone coronary artery bypass graft surgery or percutaneous coronary intervention within the last year
- B. Female older 21 years of age

- Mean age 61 y.o.
- Male 69%



28





Carlson, J. J., Norman, G. J., & Feltz, D. L. (2001) [34]

- A. First-time referrals to a cardiac rehabilitation program
- B. Patients in age between 35 and 75 years old
- C. Availability of the facility within 30 miles (48 kilometers)

Male – 80%

- Caucasian 94,5%
- College level of education or higher 53%
- Married 86,5%
- ➢ History of smoking − 61,5%
- Obesity

B. Intervention program design

Analysis of the selected studies allowed disclosing and summarizing of the main components of the intervention programs and interventions. Generally, the proposed interventions did not significantly differ from the usual rehabilitation programs, except for the study examined the effect of intervention with technology-based nature [29]. The diagram further pictures a brief scope of interventions' components discussed in the studies (*see Figure 4, Design components in the selected intervention studies*).

As it stated above, only one intervention was based on the use of information technology, and was introduced as an *exergame* [29] – a technology-based game targeting leisure exercise such as bowling, tennis, baseball, golf and boxing games. Six other studies could be considered as modified traditional programs in regard with a design.

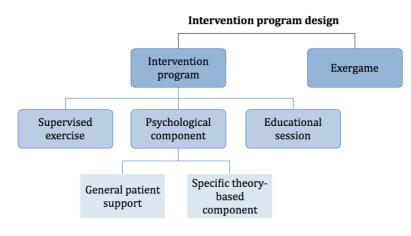


Figure 4. Design components in the selected intervention studies

The longest and most comprehensive *lifestyle intervention program* [28] consisted of two phases. The first "*heart school*" phase took place on the basis of rehabilitation center, and lasted for 6 weeks. The school was attended by patients twice a week for a *supervised exercise*, and as an addition, for *psychological support* in the form of patient motivation, identification of psychosocial problems, stress reduction, vocational and everyday life counseling. The second phase lasted for nine weeks, during which patients attended supervised exercise sessions for increasing exercise intensity level twice a week. Every three months within two years, patients were asked to attend *educational sessions* related to a heart condition provided by nurses.



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Other six studies were based on the theory-based psychological component as a key in the development and use of the interventions. Considering the design of each of these in greater details, the first, *theory-based self-efficacy coaching intervention* [30] was based on the promotion of independent exercise for adopting and maintaining a healthy lifestyle, including sufficient level of physical activity. The intervention could be represented as a supplement to a traditional cardiac rehabilitation program. The structure of the intervention included *exercise sessions* and *educational sessions* three times a week. However, the key component was the process of *coaching* to build *task and barrier self-efficacy* to independent exercise.

The second, *theory-based behavioural intervention* [31] was based on the *action and coping planning*. The methodology was represented by three main steps: action planning (i.e. when, where, how, with whom the activity is planned to be performed), coping planning (i.e. plans to overcome barriers), and he last part was supported by a *phone reinforcements* for two times along the whole program. Patients were asked to perform regular leisure exercise (such as walking and cycling) three times a week for 30 minutes, and increase everyday physical activity (for example, instead of use of elevator – choose stair climbing).

The third intervention program with underlying theory from the psychology domain was a *planned, structured exercise program* [32]. The program was provided as a *written exercise program description* for high intensity interval training. The program consisted of three independent exercise session a week, and monthly supported by *supervised exercise* sessions at the hospital.

Another comprehensive theory-based intervention program was represented as *gender-tailored*, and was designed identically to the traditional cardiac rehabilitation program except all participants were females [33]. The program was based on the *Transtheoretical Model* (TTM) *of behavior change* and delivered with 2-times individual *motivational interviewing* as a psychological component of the program design. Additionally, the tailoring mechanism was extended by providing participants with an individualized report to facilitate forward stage, tailored on TTM constructs (i.e., stage of change, decision balance, self-efficacy, and processes of change) through TTM expert system assessment, developed by "Pro-Change Behavior Systems".

The last selected intervention program was based on *Bandura's self-efficacy theory* to promote independent exercise self-efficacy [34]. In the program design, such components as verbal *persuasion, vicarious learning*, and *discussions* on patients' exercise performance and psychological states were addressed. The program was supported by *education sessions* for increasing patients' knowledge and supporting patients through weekly forum/meetings.

C. Outcomes

The effectiveness of selected interventions from the perspective of patient behavior change is to increase and maintain patients' adherence to physical-activity-related behaviour, including independent and controlled exercise, and everyday physical activity. Based on the analyzed intervention programs, it is not possible to draw definite conclusions regarding the





effectiveness of a particular intervention methodology to a group of patients with heart disease. As previously noted, for each group of patients under selected studies, it was characterized accompanying dominant variables, which should not be ignored while choosing the intervention to achieve and maintain desirable physical-activity related behavior in patients with heart disease (*see Table 6, Dominating patient-related variables in the selected intervention studies*). However, based on the studies outcomes, the following further diagram is visualizing the effectiveness of overviewed intervention programs, considering variables predicted adherence to a precise physical-activity-related behaviour (*see Figure 5, Predictors of physical-activity-related behaviour in the selected intervention studies*).

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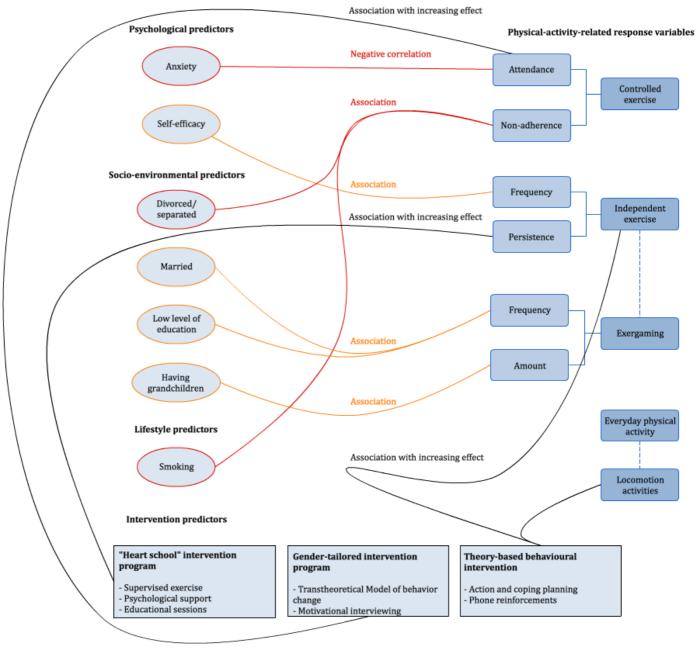


Figure 5. Predictors of physical-activity-related behaviour in the selected intervention studies



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Two interventions have shown no significant effect on the increasing patients activity levels for the independent exercise [30,32]. In one of the interventions with exergame considered as independent exercise in leisure [29], minor prognostic indicators for longer play included such socio-environmental variables as "being married" (p-value=0.082) and "having lower level of education" (p-value=0.066); for more frequent play – "having grandchildren" (p-value=0.024). Statistically significant results for increasing adherence to independent exercise (p-value<0.01), physical activity in leisure (p-value<0.01), and locomotion activity (p-value<0.01) after 2 months from the baseline were documented in the study with action and coping planning-based intervention [31]. The greatest effect among selected intervention studies has had a «heart school» intervention by maintaining patients adherence to the independent exercising for more than an hour a week after 6 months (p-value<0.001) and 2 years (p-value<0.01) from the baseline [28]. Studied gender-tailored intervention program itself was a predictor of controlled exercise attendance (p-value<0.001) [33].

Two intervention studies have had in focus other variables with a prediction power of patient physical-activity-related (non-) adherence [33,34]. Outcomes of the same gender-tailored study showed that "smoking", "being divorced or separated", or "having an anxiety" had the same statistical significance (p-value<0.001), and predicted patient non-adherence to the on-site exercise attendance; "having a depression" variable didn't show statistical significance to be an adherence predictor [33]. In the last analyzed intervention study, psychological predictor "self-efficacy" showed statistical significance (p-value<0.01) for independent exercise frequency, while second hypothesized "social support" variable did not [34].

D. Limitations

In order to understand what could affect the interpretation of the outcomes, limitations of the studies have been considered. For better visualization of the vulnerable parts of the studies and directions to which they belong, all limitations were divided into groups according to its relation to one or another part of the study (i.e., general scope of the study, study population, measurements, intervention design, and outcomes).

The table further provides a sheet of primarily limitations, which were mainly noted by the authors of the studies. Other uncertainties in studies' designs, interventions and interpretation of the results that were not included by authors, but have been additionally noticed, are documented in the table as well (*see Table 7, Limitations of the selected intervention studies*).

Table 7. Limitations of the selected intervention studies

Limitations

	≻	Limited number of participants
General scope of the study	≻	Relatively short studies duration
	≻	Study organization issues





Study population	 Age and gender domination Uncertainty of other present patient-related variables
Measurements	 Subjectivity of major measurements Technical issues in objective measurements
Intervention design	 Similarity to traditional intervention programs design Lack of tailoring methodologies
Outcome	 Uncertainty of intervention program effect

Limited number of participants: In all selected studies, patients' population did not exceed number of 252; the mean number of patients in the selected studies was counted to 118 (min=32, max=252) [28,33]. It is necessary to note that the number of included patients has not always been counted similarly. For example, in two studies the number of included patients was 75 and 144. However, the results for the intervention effectiveness analysis were collected from 65 (out of 75) and 136 (out of 144) patients [30,31]. At the same time, in another study, 220 patients have been initially selected, but the authors stated 197 as a number of patients included [28].

<u>Relatively short study duration</u>: The duration of the studies ranged from 12 weeks to two years. Taking into account the results of studies with two-year period of investigation, patient adherence to physical-activity-related behaviour is a dynamic indicator, which tends to deteriorate, as with time, the effect of intervention on adherence is prone to be noticeably reduced. This indicates that in order to ensure adherence maintenance process, it is necessary to conduct longitudinal studies [28].

<u>Study organization issues:</u> One of the limitations noted by the authors, is the lack of a control group [29]. In this case, to consider the impact of the developed intervention, it is necessary to conduct a follow-up study with both, intervention and control groups. Another highlighted study organization limitation included different rates of patient participation due to effect of different health insurance programs of participated in the study patients [30].

<u>Age and gender domination:</u> Majority of participants in all the selected studies are men, and patients of older adults age group [28,29,30,31,32,34]. Such dominations should be taken into account due to its potential to effect patient acceptance of a precise intervention and its settings. For example, in one of the studies, the authors noted that adherence to the intervention was greater in men [29]. However, the fact that the intervention, which was represented by an exergame, included such games as bowling, tennis, baseball, golf, and boxing games was not taken into account. In this case, a gender-dependent divergence of interests in leisure activities could potentially play a crucial role in acceptance.

<u>Uncertainty of other present patient-related variables:</u> In the selected intervention studies, little attention was given on the cognitive and psychological patient-related variables, while it could help to understanding necessary interventions' readjustments and generally the



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interventions" outcomes. In the study, the authors indicated that the possible lack of the expected effect of the intervention was due to the fact that the studied group of patients was already motivated [30]. However, this parameter was not taken into account. Other authors also highlighted the unpredictable effect of omitted variables [33].

<u>Subjectivity of major measurements</u>: Authors of the majority of the selected studies have noted the subjectivity of physical-activity-related behaviour measuring; self-reported diary was the leading measurements instrument [28,29,30,31,32,34]. However, the method does not exclude the likelihood of inaccurate reported data. For example, a patient could forget to document the activity, or in an opposite, record an exercise session that has not been performed.

<u>Technical issues in objective measurements:</u> It was noted that the devices used to measure patients' physical activity could have been worn improperly in order to keep patients' comfortable while wearing. This fact could potentially affect the measurements [29].

<u>Similarity to traditional intervention programs design</u>: The authors of one of the studies noted that the intervention content and design was not dissimilar enough in a way to show outcome which will not only will differ with outcome of the control group but also support the purpose of behaviour change and further maintenance [30].

Lack of tailoring methodologies: Despite the fact that only one author referred to the lack of methodology considering an individual approach to the patients [30], design of interventions in six out of seven intervention studies did not include tailoring component based on other variables than having a heart disease and being subscribed to a cardiac rehabilitation program.

<u>Uncertainty of intervention effect</u>: Another limitation is not clear nature of intervention effect. In one of the studies, authors argued about the uncertainty of the effect of intervention due to its presence as a part of a rehabilitation program [30]. The rehabilitation program could possibly cause the effects itself. In another study, it was observed that the positive effect of the intervention presented a statistical significance. However, the control group also had a statistical significance in the increasing physical activity level [31]. From this fact, it can be concluded that the power of intervention's effect has not been clearly proven.





Chapter 4. Summary of Findings

4.1 Overview of physical-activity-related adherence research in patients with heart disease

Based on the examined studies, several particularities in regard to study population and settings, physical-activity-related adherence, as well as factors influenced adherence and interventions directed on adherence modification and maintenance, which could potentially influence obtained findings, were observed.

<u>Study population</u>: In most studies, the patient groups were represented by the male gender. It's worth noting that men not only have different anatomical organization, considered in the context of physical exercise, but also other life commitments than women. For instance, women tend more to do the housekeeping, which cannot but influence the psychological and physiological state (e.g., feeling fatigue after work done at home). This means that the examination of certain groups of factors should be within the framework of the study with the same gender, or the differentiation between them. Similarly, with no exception, the mean age of patients belonged to older adults, while age of patients with heart disease decreases as it was noted earlier (*see Section 1.2, Physical-activity-related adherence in patients with heart disease*). Despite the fact that patients in all studies had heart disease, groups of patients in different studies had different characteristics could affect the results of studies in general.

<u>Study settings</u>: Majority of the studies that examined physical-activity-related adherence after cardiac rehabilitation enrollment were of relatively short duration (up to 2 years) and often limited to small sample sizes. Additionally, it is important to mention that the examination of patient adherence within the cardiac rehabilitation programs could be affected by its settings; programs differed from each other (i.e., high intensity, low intensity, with or without educational and psychological component, etc.).

<u>Physical activity-related adherence:</u> The selected studies provide many types and specifications of adherence, depending on the particular physical-activity-related behaviour (i.e., exercise, everyday physical activity), its dimensions (i.e., frequency, amount, etc.), and settings (i.e. controlled or home-based environment) (*see Section 3.1, Physical-activity-related behaviour: types, settings, and measurement criteria*). Thus, adherence to recommended behaviour described by such terms as "poor", "partial", "good", and "full", while to refer to the complete decline in following with medical recommendation, the terms "non-adherence" or "dropout" were used. Various behaviours of patients were described in regard to lack of adherence. Not following medical recommendations can span from rejecting cardiac rehabilitation program, to preforming exercise with not sufficient level of intensity, irregular physical activity in general, etc. Special attention should be paid to the measurement methods and instruments that have been used in the studies. The leading method measuring independent exercise adherence was subjective, and was completed by the documentation of physical-activity-related behaviour by patients themselves or by answering on questions related to performed activity. In some studies, adherence to physical



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activity has been examined as a part of lifestyle recommendations adherence, together with medication or/and diet; in these studies the assessment of adherence could be described as poor due to addressing only one or two questions with regard to physical-activity-related behaviour. Adherence to controlled exercise was based on rehabilitation program attendance, and was counted by the percent of overall attended sessions. However, in the studies, the level of adherence and determination of "dropout" was considered in different ways or was not determined or specified at all.

Factors: The biggest challenge, which limits the current understanding of the influence of certain factors when considering the investigation adherence is multifactorial. The recent literature review shows that patient adherence determined by many factors, including demographics, socio-environmental, anthropometrical, clinical, health care-service-related, cognitive and psychological, physiological and physical-activity-related, and lifestyle factors (see Section 3.2, Factors associated with physical-activity-related adherence). It is important to note that most of the factors depending on the study were positioned as both, significant and not significant. It was also documented that the same factor could be oppositely associated with adherence. This indicates that while studying patient adherence, it is necessary to consider and include as many study population variables as possible. Of all the examined studies, the lack of investigation of daily lifestyle factors (e.g. sleep, diet habits) on physical activity adherence patterns should be considered with a special attention. Lifestyle factors may not directly influence adherence to physical activity, but through the other patients' states. For example, the lack of sleep leads to fatigue and low mood, which can cause a physiological discomfort and lack of physical ability and emotional desire to perform an exercise. It shows that the presence (or absence) of any single factor may affect the adherence in general, which is why a comprehensive approach to studying associated factors is important in the domain of (non-) adherence formation.

<u>Interventions</u>: The investigation of specific interventions was not the focus of the recent literature review. However, few intervention-focused studies found in the search results were separately analyzed (*see Section 3.3, Compliance change power of specific intervention programs and interventions*). Only a few papers examined the impact of specific intervention programs or interventions, and only in one study the investigated adherence was to physical activity-related behaviour with patients engaged in technology-based intervention (i.e. exergame). Overall, considering the impact of particular overviewed interventions is difficult enough due to the ambiguity of the obtained results. Most intervention programs did not differ from those that have been used in control groups, while is some studies there was no control group. Investigation of studies with specifically designed interventions requires a separate examination.

4.2 Concluding remarks and practical suggestions

First of all, it has to be mentioned that the analyzed studies are only the part of the worldwide available studies that could potentially be included within the research domain of the presented literature review. However, selected papers have been shown to be enough to become familiar with the practical side of the domain of patient adherence, to understand





the directions for further investigations, and to consider practical actions that should be targeted in the study of physical-activity-related adherence in patients with heart disease.

<u>Research taxonomy</u>: The most important and necessary action that should be deliberated in the research of physical-activity-related adherence in patients with heart disease is a development of a taxonomy. Such tool would make it possible to carry out further investigations, the results of which would be not only reusable due to its defined frame and components, but also could be used in the organization and development of interventions.

<u>Modifiable factors analysis:</u> Not all the associated influence factors can be eliminated or mitigated, but it is necessary to know their existence and possible impact or affect. The issue of dividing factors to modifiable and non-modifiable, from the perspective of their use in interventions under different settings (e.g., technology-based, traditional interventions, etc.) requires further investigation.

<u>Prediction algorithm</u>: A deeper investigation of interventions and strategies behind, its design and factors that already are addressed in the design is a necessity, in order to achieve better interventions' tailoring, and development in general. With respect to the investigated in the presented literature review domain, and the concept of Connected health, particular attention has to be paid on technology-based interventions that already exist as concepts, tested tools, or products used in the clinical practice for patients with heart disease. Due to the rapid development of technology, particular attention has to be paid to the search for such interventions and strategies using patent databases. The investigation of the aforementioned, together with the results of the presented review, may serve a solid background for the development of the prediction algorithm for early identification and prognosis of patients' (non-) adherence, and as a result, intervention tailoring, further behaviour modification and maintenance.

In the conclusion, it should be said that the presented in the literature review analyses highlight a general representation of adherence to physical-activity-related behaviour and associated factors. Deeper analysis, examining each particular behavior (i.e., controlled exercise, independent exercise, etc.) and addressed in the review factors, as well as a number of other analyses, is scheduled to be released later in 2016.





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Appendixes

Appendix 1. Databases search strategies

Database	Search string
	Preliminary search strategy
PubMed	(physical activity[Title/Abstract] OR exercise[Title/Abstract]) AND (adherence[Title/Abstract] OR compliance[Title/Abstract]) AND (heart failure[Title/Abstract] OR cardiac rehabilitation[Title/Abstract] OR



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	coronary artery disease[Title/Abstract]) AND (barriers[Title/Abstract] OR
	correlates[Title/Abstract] OR predictor[Title/Abstract] OR
	predictors[Title/Abstract])
Cochrane	#1 physical activity or exercise
Library	#1 physical activity or exercise#2 adherence or compliance
2101019	#3 barriers or correlates or predictor or predictors
	#4 #1 and #2 and #3 with Heart Group in Review Groups
	Search strategy using MeSH
PubMed	(((factors[Title/Abstract] OR barriers[Title/Abstract] OR "risk
	factors"[Title/Abstract] OR determinants[Title/Abstract] OR
	correlates[Title/Abstract] OR predictor[Title/Abstract] OR
	predictors[Title/Abstract] OR relationship[Title/Abstract] OR
	relationships[Title/Abstract] OR association[Title/Abstract]) AND
	((adherence[Title/Abstract] OR "patient compliance"[MeSH Terms] OR
	patient compliance[Title/Abstract] OR "compliance"[MeSH Terms]) AND
	("motor activity"[MeSH Terms] OR motor activity[Title/Abstract] OR (physical[Title/Abstract] AND activity[Title/Abstract]) OR "exercise"[MeSH
	Terms] OR exercise[Title/Abstract] OR "physical fitness"[MeSH Terms] OR
	physical fitness[Title/Abstract]))) AND (influence[Title/Abstract] OR
	predict[Title/Abstract] OR associate[Title/Abstract])) AND ("heart
	failure"[MeSH Terms] OR ("heart"[Title/Abstract] AND
	"failure"[Title/Abstract]) OR "heart failure"[Title/Abstract] OR "heart
	diseases"[MeSH Terms] OR "heart diseases"[Title/Abstract] OR "heart diseases"[Title/Abstract] OR "coronany artery diseases"[MeSH Terms] OR
	disease"[Title/Abstract] OR "coronary artery disease"[MeSH Terms] OR "coronary artery disease"[MeSH Terms] OR ("coronary artery
	disease"[MeSH Terms] OR ("coronary"[Title/Abstract] AND
	"artery"[Title/Abstract] AND "disease"[Title/Abstract])) OR cardiac
	rehabilitation[Title/Abstract] OR (("heart"[MeSH Terms] OR
	heart[Title/Abstract] OR cardiac[Title/Abstract]) AND
	("rehabilitation"[Subheading] OR rehabilitation[Title/Abstract] OR
	"rehabilitation"[MeSH Terms])))
Cochrane	#1 factors or barriers or determinants or correlates or predictor or
Library	predictors or relationship or relationships or association or risk factors
	#2 adherence or patient compliance or (patient near/2 compliance) or
	compliance#3 MeSH descriptor: [Patient Compliance] explode all trees
	 #3 MeSH descriptor: [Patient Compliance] explode all trees #4 MeSH descriptor: [Compliance] explode all trees
	#5 #2 or #3 or #4



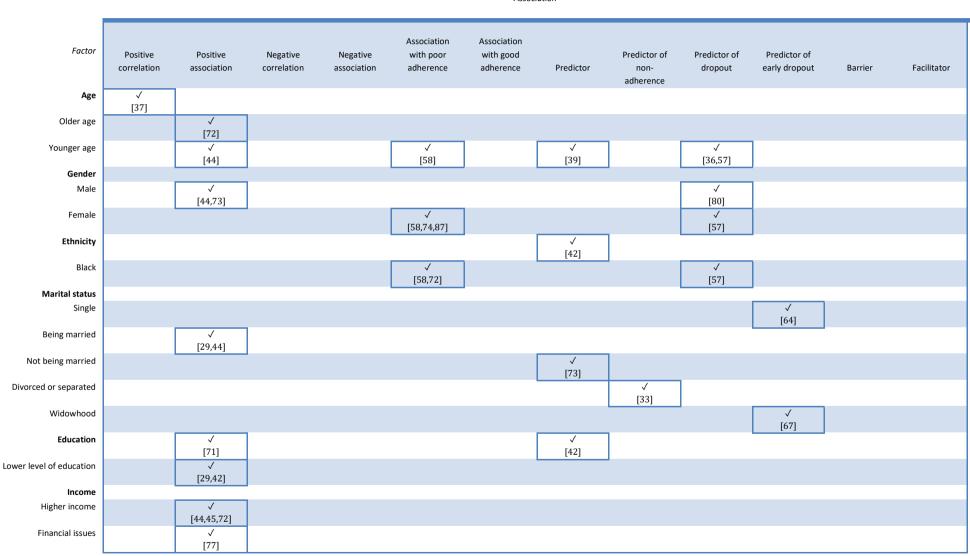


#6	motor activity or physical activity or (physical near/2 activity) or
exerc	ise or physical fitness
#7	MeSH descriptor: [Motor Activity] explode all trees
#8	MeSH descriptor: [Exercise] explode all trees
#9	MeSH descriptor: [Physical Fitness] explode all trees
#10	#6 or #7 #8 or #9
#11	influence or predict or associate
#12	(#5 and #10) and #1 and #11 with Heart Group in Review Groups

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Appendix 2. Demographic factors associated with physical-activity-related adherence

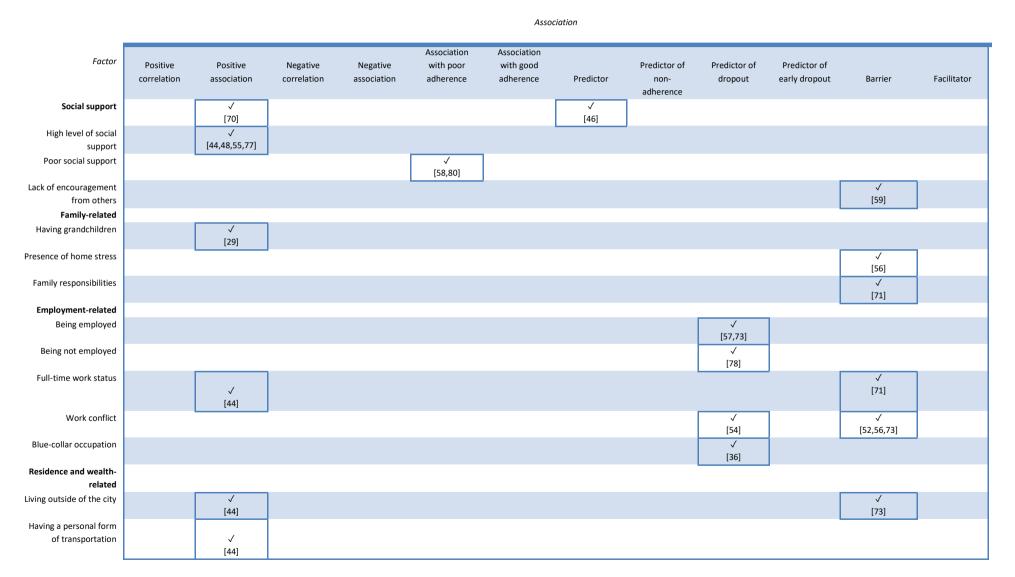




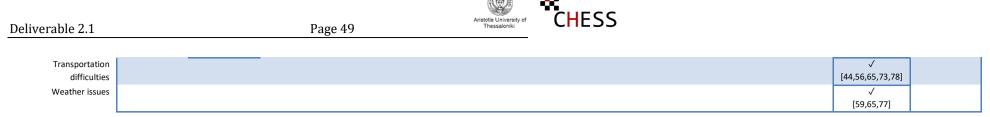
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Appendix 3. Socio-environmental factors associated with physical-activity-related adherence







Association

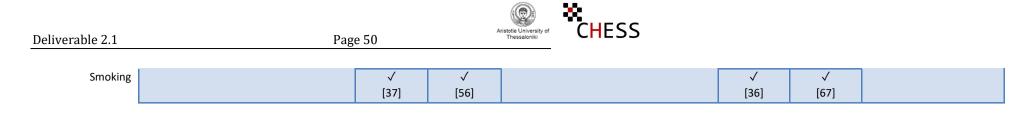
Appendix 4. Anthropometric factors associated with physical-activity-related adherence

Factor Association Association Predictor of Predictor with good Positive with poor Positive Negative Negative non-Predictor of early correlation adherence adherence correlation association association Predictor adherence of dropout dropout Barrier Facilitator Body mass index \checkmark [37] (BMI) \checkmark \checkmark \checkmark **Higher BMI** [58] [57] [67] Overweight \checkmark [64] Obesity \checkmark \checkmark [69] [43] \checkmark Lower BMI \checkmark [39] [53] Sum of three \checkmark [37] skinfolds

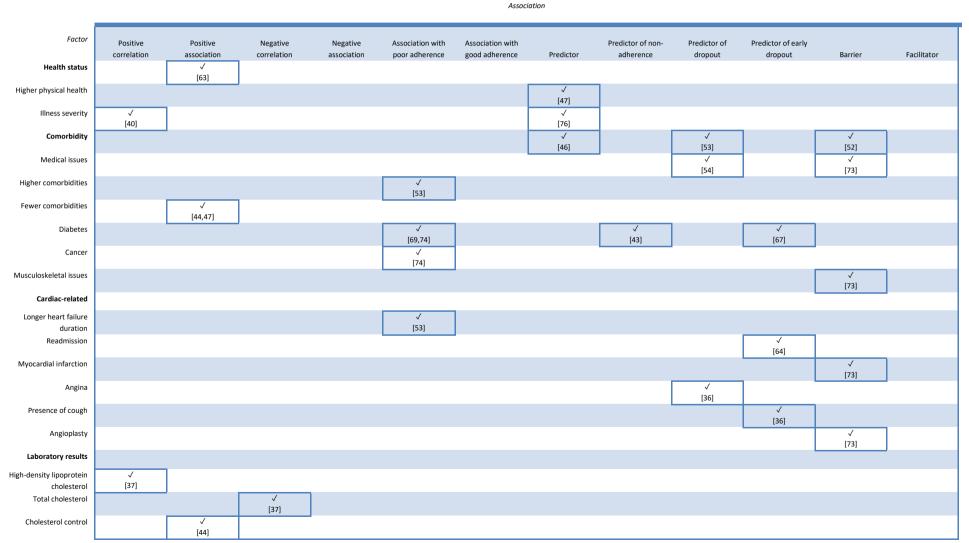
Appendix 5. Lifestyle factors associated with physical-activity-related adherence

Factor	Positive	Positive	Negative	Negative	Association with poor	Association with good		Predictor of non-	Predictor	Predictor of early		
	correlation	association	correlation	association	adherence	adherence	Predictor	adherence	of dropout	dropout	Barrier	Facilitator
Lifestyle habits												





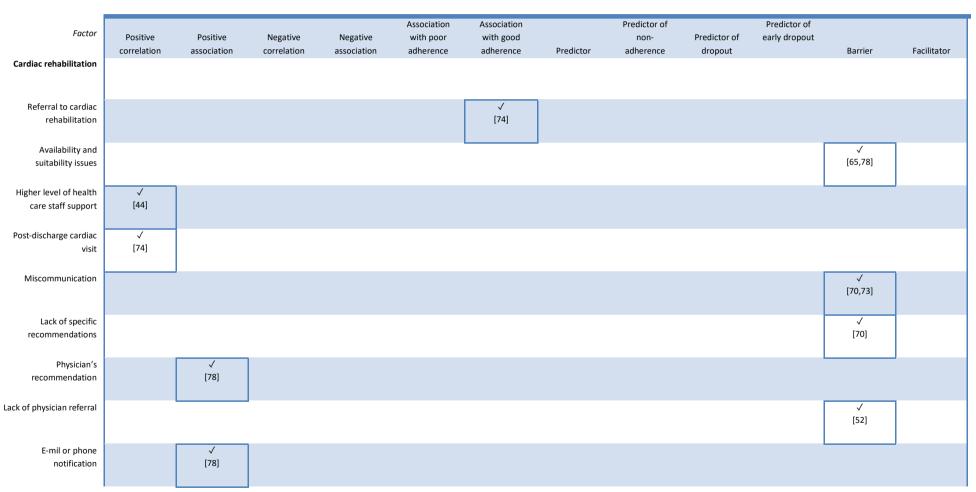
Appendix 6. Clinical factors associated with physical-activity-related adherence





Deliverable 2.1	Page 51	
Triglycerides	√ [37]	
Medication		
Antidepressant medication		√ [64]

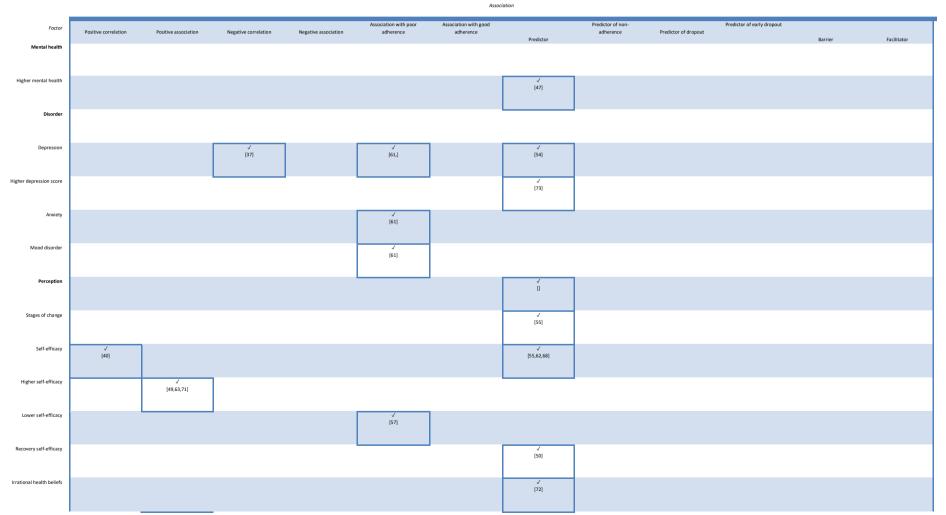
Appendix 7. Health care service-related factors associated with physical-activity-related adherence







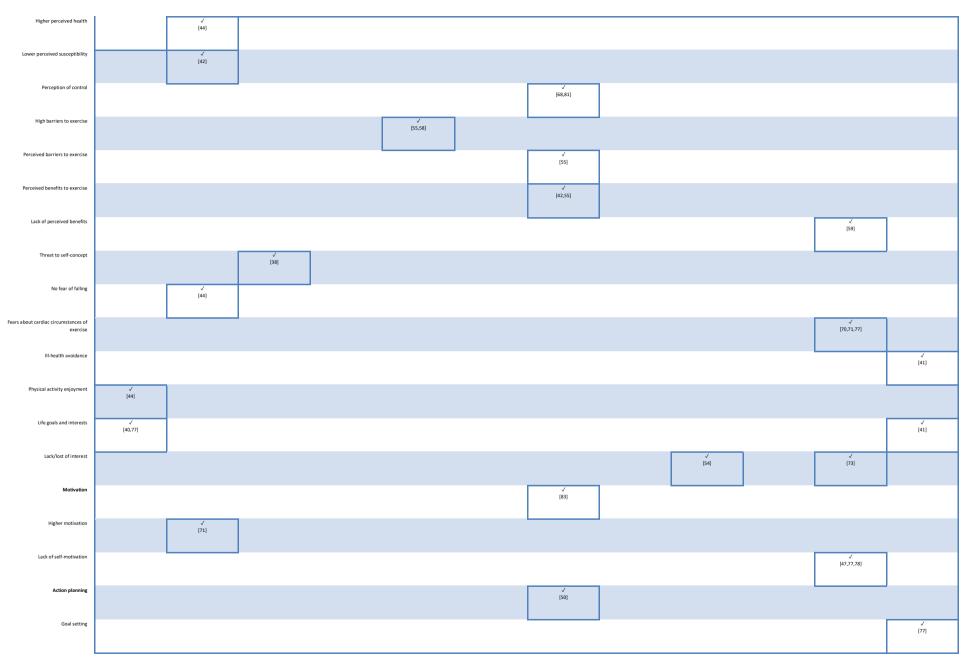
Appendix 8. Cognitive and psychological factors associated with physical-activity-related adherenc



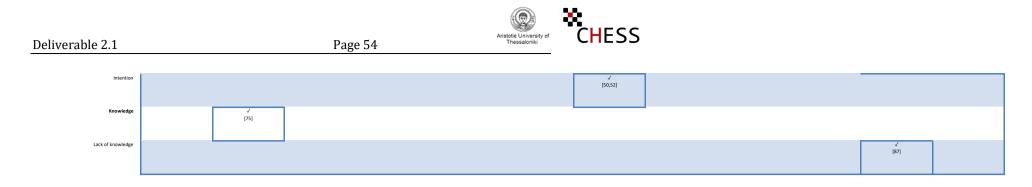




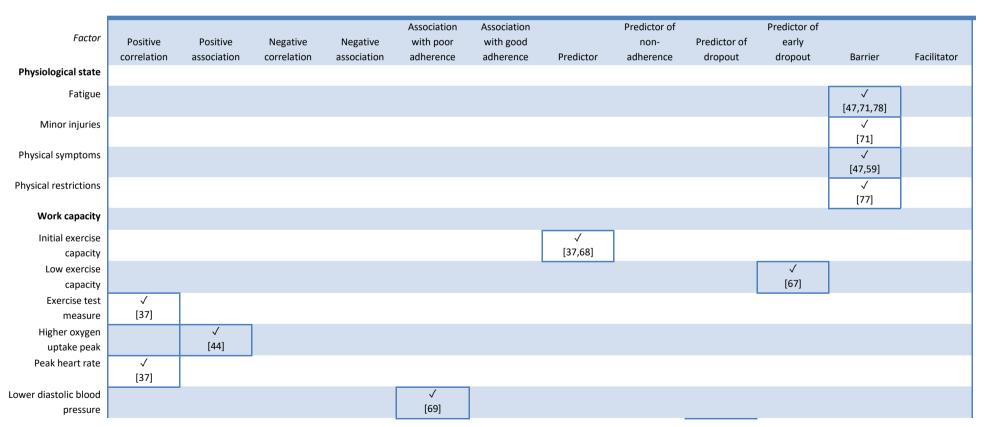




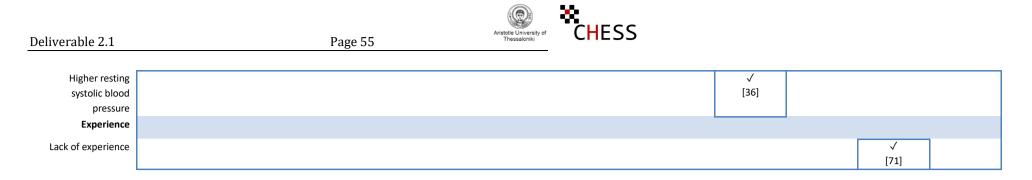




Appendix 9. Physiological and physical-activity-related factors associated with physical-activity-related adherence







Appendix 10. Combination of factors associated with physical-activity-related adherence

Factor	Positive correlation	Positive association	Negative correlation	Negative association	Association with poor adherence	Association with good adherence	Predictor	Predictor of non- adherence	Predictor of dropout	Predictor of early dropout	Barrier	Facilitator
Older patients with comorbidity					√ [66]							
Family history of coronary disease (men)							√ [56]					
Asian women					√ [51]			-				
Younger women					√ [56]							
Older women						√ [56]						

