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The advancement of medical science requires basic investigation into the mechanisms of disease, improvement in clinical diagnosis and risk stratification, and development and testing of new therapies to substantiate their safety and efficacy. The HRFUP has been involved in the design, conduct, and analysis of local and world-wide, multicenter, clinical research studies for 30 years. The studies have ranged from small or large observational studies to Phase IV clinical trials testing specific drug or device intervention. These studies use the latest basic science, bioengineering, genetic, biostatistical, physiological, and clinical approaches to optimize the acquisition of new knowledge in order to improve the diagnostic and therapeutic foundation of clinical medicine. Commitment to Excellence in Research In all of the studies, the HRFUP has consistently met specified enrollment numbers by recruiting strong capable enrolling center investigators, effectively coordinated multicenter activities including maintenance of regulatory standards, maintained proper quality control of large amounts of data, used sophisticated multivariate analytic methods, published definitive reports in major journals in a timely manner following completion of each study, and assisted with data submissions as requested by the study sponsors and the FDA. One hallmark of the HRFUP is to statistically design cost-effective studies using sequential analysis techniques to potentially allow for early study termination. As an academic-based, full-facility research center with access to a vast array of University based services, the HRFUP can provide the highest professional standards to meet all aspects of the diverse management requirements of cardiovascular research studies of clinical cardiology. The HRFUP research interests include but are not limited to cardiovascular physiology, cardiac arrhythmias, sudden death, myocardial infarction, posthospital phase of myocardial infarction, heart failure, ventricular repolarization, thrombogenic factors and pharmacoeconomics. The HRFUP also actively collaborates with various departments at University of Rochester Neurology, Pulmonology, Environmental Diseases, Pediatrics, Community and Preventive Medicine on studies involving cardiovascular research in relationship to neurologic disorders, asthma and COPD disorders, environmental exposure to air pollution and mercury. The main focus of this research is on ventricular arrhythmias, electrocardiology in relationship to diagnosis and prognosis of entities predisposing to ventricular arrhythmias and sudden death. Numerous research projects have stemmed from this activity over the years. Our ECG Core Lab established standard adopted now world-wide for high-resolution Holter recordings in clinical studies. Our collaboration with Electrical Engineering Department and training fellows in the field of bioengineering resulted in the advancement of ECG signal processing focused on QT measurements, ST segment monitoring, T wave alternans, T wave variability, and recently on T wave morphology. These advances together with our history of clinical research in the field of electrocardiology led to establishing the Center for Quantitative Electrocardiology and Cardiac Safety. This Center strives to 1 develop specific projects to implement and grow the repository of ECG information; 2 facilitate scientific projects toward the development, testing and validation of ECG-related technologies; 3 leverage expertise and resources toward the implementation of collaborative projects among the FDA, UR, and other public and private stakeholders; 4 identify, develop and evaluate new electrocardiographic markers of cardiovascular risk related to management of patient care and evaluation of new molecular entities; and 5 incorporate scientific findings into the premarket evaluation process for electrocardiographic devices and associated methodologies, and into the total product life cycle. Most recent work led to the development of novel technologies for contactless monitoring of patients Xerox Corp. Each year cardiology fellows, residents, and students work in HRFUP to obtain experience and training in translational clinical cardiac research. Investigator Experiences Wojciech Zareba, M. Studies conducted by Dr.

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Moss led to new indications for implantable cardioverter-defibrillators exercised in thousands of patients worldwide. He has patented and licensed multiple technologies developed at UR. Dr, Couderc is the scientific founder of local startup company and the Director of the Center for Quantitative Electrocardiography and Cardiac Safety. She is an expert in the field of Cardiac Resynchronization Therapy and Heart Failure Clinical Trials with extensive clinical experience and she has numerous research collaborations in the U. Brown has excellent expertise in methodology and conduct of clinical trials â€" she has been serving as main study coordinator for numerous studies and trials. Web of Science Results Found:

Chapter 2 : Exercise-based cardiac rehabilitation in patients with coronary heart disease: a practice guideli

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The purposes of the VMI are to help identify, through early screening, children who may need special assistance, to obtain needed services, to test the effectiveness of educational and other interventions, and to advance research. The short form has 21 items and is for children years of age. The full form has items and can be either group or individually administered in minutes for ages Reliability and validity are discussed and norms are provided. Also included in this edition are norms for two-year old children; developmental stepping stones norms for birth through age six and visual-motor teaching methods from birth through early elementary school. There is an item version for ages 3 to 7, and a item version for use with preschool children through adults. It may be used as an aid in diagnosing the difficulties of emotionally disturbed and brain damage. The second edition has seven new designs to increase the ability range. A recall phase and two supplementary tests the Motor Test and the Perception Test have been added. New Norms are provided. There is no time limit. Reliability and validity are discussed. Bender Visual Motor Gestalt Test For Children Provides an index of structural and functional aspects of perceptual motor development. Used as an aid in diagnosing the difficulties of emotionally disturbed children and identifying organic brain damage. Requires copying of nine designs. These nine figures were adapted from the original Wertheimer version which required only a verbal description of the figures. The figures were simplified and adapted to accentuate particular Gestalt figures. It provides information for interventions such as individual family plans, individual educational plans, career assessment, work transition, career change, employee selection and adult neuropsychological treatment. It may be useful in a variety of forensic contexts. It has been used to diagnose mental retardation, learning disabilities, developmental cognitive delays in young children, as well as placement of students in school programs for the intellectually gifted. The examiner must be professionally trained and certified. The Stanford Binet, Fifth Edition SB5 is an individually administered assessment of intelligence and cognitive abilities. The complete scale consists of 10 subtests: It takes 15 minutes to administer depending on the scale administered. Differences in this edition include: Half of the subtests use a nonverbal mode of testing. New Items include very low and very high discriminating items. Instrument is comprised of five subtests of the fourth edition which were determined to require the least amount of verbal response. Technical data are included. Stanford-Binet Intelligence Scale, Fourth Edition This revision of the edition is individually administered to children from below age 2 through superior adults. Tests cover four major areas: Scores include raw scores and scaled scores for each of the 15 subtests, scaled scores and percentile ranks for a composite of the four area scores, a composite of any combination of the four area scores and a profile of all 15 subtests, based on scaled scores. Separate norms are provided for each score. A pretest is administered to identify the level at which to begin testing. The test is said to have minimal sex or ethnic bias. Adult norms are for the age group. Wechsler Adult Intelligence Scale - Third Edition The Wechsler Adult Intelligence Scale, Third Edition is an individually administered clinical instrument designed to assess the intellectual ability of adults ages 16 through The test yields the three traditional composite IQ scores - verbal, performance, and full scale - and four index scores - verbal comprehension, perceptual organization, working memory, and processing speed. The WAIS-III can be used as a psychoeducational test for secondary and postsecondary school planning and placement and also for differential diagnosis of neurological and psychiatric disorders that affect mental functioning. Item content, administration and scoring procedures of all subtests were revised. Five new subtests were added: Wechsler Intelligence Scale for Children, Third Edition A clinical instrument for assessing the intellectual ability of children ages 6 through 16 years. Subtests are organized into two groups: Wording was revised on some items. Outdated items were deleted and ethnicity and gender references were balanced. Biased items were also revised. Provides current normative data. The test consists of 11 subtest, with 6 primary subtests and 5 optional subtests. The primary subtests are: The primary subtests can be

administered in approximately minutes. The optional subtests are: WMS-II was designed to provide relevant information for general clinical and neuropsychological evaluations and for rehabilitation evaluations. Word reading measures letter and word decoding through letter identification and word recognition. The test can be administered to individuals ranging in age from 5 through 94 years old. The purpose of the test is to measure the codes needed to learn the basic skills of reading, spelling, and arithmetic. It was designed to eliminate as much as possible the effects of comprehension. Norms and reliability data are provided. Absolute scores, standard scores and grade scores are provided for each of the three subtest areas. When used in conjunction with a test measuring general intelligence which has the same standard deviation units, it can be use to help determine learning ability or learning disability. Tests of Achievement and Tests of Cognitive Abilities. The two batteries assess general intellectual ability, specific cognitive abilities, oral language and academic achievement. The achievement battery is available as a standard battery comprising 12 tests or an extended battery that has 10 tests that provide more in-depth diagnostic information on specific academic strengths and weaknesses. The achievement tests are primarily organized into five broad curricular areas: The test is also available in two forms, form A and form B, that have parallel content. The two batteries assess general intellectual ability, specific cognitive abilities, oral language, and academic achievement. The Tests of Cognitive Abilities is comprised of a standard battery tests and an extended battery tests 11 - The tests assess the following cognitive factors: These techniques are individually available from the publisher. Rorschach Interpretive System A scoring method allowing for the input of raw Rorschach data gathered by physician or clinical and interpretation via a scoring system by John E. A narrative report and a record of the raw data are provided. Narratives describe psychological state, trait characteristics, and defense mechanisms. It is part of a package with 28 instruments and hardware. The system is designed to administer, score, interpret or supply results of testing within a few minutes. Subject is asked to draw pictures of a house, a tree, and a person. Subject is given an opportunity to explain the drawings. Kinetic Drawing System for Family and School A projective technique, used to help understand the dynamics of self growth in family and school. Composed of two separate instruments: Especially useful with children who have difficulty with verbal expression. Thematic Apperception Test Designed to elicit interpretations by subject of social situations. Stories and descriptions of pictures reveal some of the dominant drives, emotions, sentiments, conflicts, and complexes of a personality. It is suggested that examinee review only ten pictures at each of two sessions. Bellak TAT Blank and Analysis Sheet may be used by the psychologist to provide a more definite frame of reference and a more objectively comparable scheme of interpretation. MMPI-2 test booklet is revised. National norms have been restandardized and are more representative of the present U. Scores from the restandardization subjects on eight of the Basic Clinical Scales are uniform T scores. New scales are offered that provide protocol validity; new content dimensions; and separate measures of masculine and feminine gender roles. Minnesota Multiphasic Personality Inventory - Form R Designed for use with adolescents and adults who have psychological or psychiatric difficulties. Provides clinical psychologist with information regarding treatment decisions and treatment evaluation. Identifies psychiatric symptomatology and personality dynamics. Form R consists of true-false items which may be administered in approximately ninety minutes to an adolescent or adult with a minimum sixth-grade reading level. Changes in version III include: The assessment has items, written at the eighth-grade reading level. Most patients can complete the assessment in 20 to 30 minutes. It is normed entirely on clinical samples and norms are applicable only to individuals who evidence psychological problems or who are engaged in a program of professional psychotherapy or psychodiagnostic evaluation. JW Millon Clinical Multiaxial Inventory - II A revision of the Millon Clinical Multiaxial Inventory TC which provides information to clinicians who must make assessments and treatment decisions about persons with emotional and interpersonal difficulties. Meant to be used for diagnostic screening or clinical assessment in a wide variety of settings; and is therefore simple to administer, with rapid computer scoring and interpretation. Special population norms have been developed, including those for black and Hispanic patients. Translations available for many foreign languages. It is a item scale, self-report inventory designed specifically for

assessing adolescent personality characteristics and clinical syndromes.

Chapter 3 : Heart Research Follow-up Program - University of Rochester Medical Center

For patients with unstable angina with negative cardiac markers and ongoing angina, a combination of aspirin, heparin, and a glycoprotein IIb/IIIa inhibitor (e.g., eptifibatide [Integrilin]) is recommended. Î²-Adrenergic blockers decrease myocardial oxygen demand by reducing heart rate, blood pressure, and contractility.

Group of patients treated at a dose level. Starting dose The dose chosen to treat the first cohort of patients in a phase I trial. Dose increment decrement The percent increase or decrease between dose levels. DLTs are defined before beginning the trial and are protocol specific. They are typically defined based on toxic effects seen in the first cycle and specified using a standardized grading criteria, for example, Common Terminology Criteria for Adverse Events. Doseâ€"efficacy curve The doseâ€"efficacy curve reflects the relationship between dose and probability of efficacy for an anticancer agent. Doseâ€"toxicity curve The doseâ€"toxicity curve reflects the relationship between dose and probability of toxicity for an anticancer agent. Target toxicity level The maximum probability of DLT that is considered acceptable in the trial. Phase I trials conducted in Europe and Japan: Phase I trials that use model-based methods: Optimal biological dose OBD Dose associated with a prespecified most desirable effect on a biomarker among all doses studied eg, inhibition of a key target in tumor or surrogate tissue or achievement of a prespecified immunologic parameter. Phase I trials with a toxicity endpoint that are conducted in Europe and Japan: Phase I trials in which the endpoint is a prespecified biological endpoint: Pharmacokinetics Pharmacologic effects of the body on the drug ie, the time course of drug absorption, distribution, metabolism, and excretion. Pharmacodynamics Pharmacologic effects of the drug on the body eg, nadir neutrophil or platelet count, nonhematologic toxicity, molecular correlates, imaging endpoints. Therapeutic index The dosage or range of dosages of a drug that is required to produce a given level of damage to critical normal tissues toxicity divided by the dosage or range of dosages that yields a defined level of antitumor effect efficacy see Figure 1. Open in a separate window The guiding principle for dose escalation in phase I trials is to avoid unnecessary exposure of patients to subtherapeutic doses of an agent ie, to treat as many patients as possible within the therapeutic dose range while preserving safety and maintaining rapid accrual. Dose escalation methods for phase I cancer clinical trials fall into two broad classes: The rule-based designs assign patients to dose levels according to prespecified rules based on actual observations of target events eg, the dose-limiting toxicity from the clinical data. Typically, the MTD or recommended dose for phase II trials is determined by the prespecified rules as well. On the other hand, the model-based designs assign patients to dose levels and define the recommended dose for phase II trials based on the estimation of the target toxicity level by a model depicting the doseâ€"toxicity relationship. However, because of safety concerns, most model-based designs are modified such that specific restrictions are set as safeguards for elements such as dose increments to avoid overshooting of the MTD and thus exposing patients to undue harm. All of these methods were developed in the era of cytotoxic drugs, during which time it was assumed that both efficacy and toxicity increase with dose. These relationships are typically represented by doseâ€"toxicity and doseâ€"efficacy curves in which toxicity and efficacy increase monotonically with increasing dose Table 1 and Figure 1. Consequently, these methods have used toxicity as the primary endpoint. For molecularly targeted agents, the doseâ€"efficacy and doseâ€"toxicity curves may differ from those for cytotoxic agents, and efficacy may occur at doses that do not induce clinically significant toxicity 1 â€" 4. Thus, for trials involving these agents, the occurrence of drug-related biological effects has been suggested as an alternate primary endpoint besides toxicity 1 â€" 4.

Chapter 4 : Phases of clinical trials

The pilot study using randomised controlled trial design (parallel-group trial) within the participants' usual health care environment will be conducted in three distinct but overlapping phases: (1) development of the training package including the CDSMP materials and Digital Video Disk (DVD), (2) peer selection and training, and (3) intervention phase.

Policy Aetna considers outpatient cardiac rehabilitation medically necessary as described below. Acute myocardial infarction within the preceding 12 months; or Chronic stable angina pectoris unresponsive to medical therapy which prevents the member from functioning optimally to meet domestic or occupational needs particularly with modifiable coronary risk factors or poor exercise tolerance ; or Coronary artery bypass grafting coronary bypass surgery, CABG ; or Heart transplantation or heart-lung transplantation; or Major pulmonary surgery, great vessel surgery, or MAZE arrhythmia surgery; or Percutaneous coronary vessel remodeling i. Aetna considers cardiac rehabilitation experimental and investigational for all other indications e. High-risk members have any of the following: Program Description for High-Risk Members: Intermediate-risk members have any of the following: Program Description for Intermediate-Risk Members: Program Description for Low-Risk Members: Aetna considers additional cardiac rehabilitation services medically necessary based on the above-listed criteria when the member has any of the following conditions: Another cardiovascular surgery or angioplasty; or Another documented myocardial infarction or extension of initial infarction; or New clinically significant coronary lesions documented by cardiac catheterization; or New evidence of ischemia on an exercise test, including thallium scan. Please check benefit plan descriptions. Background Patients who have cardiovascular events are often functional in society and employed prior to a cardiac event, and frequently require only re-entry into their former life pattern. Cardiac rehabilitation serves this purpose by providing a supervised program in the outpatient setting that involves medical evaluation, an ECG-monitored physical exercise program, cardiac risk factor modification, education, and counseling. Cardiac rehabilitation is designed to help individuals with conditions such as heart or vascular disease return to a healthier and more productive life. This includes individuals who have had heart attacks, open heart surgery, stable angina, vascular disease or other cardiac related health problems. Phase I cardiac rehabilitation begins in the hospital inpatient after experiencing a heart attack or other major heart event. During this phase, individuals receive education and nutritional counseling to prepare them for discharge. Phase II outpatient cardiac rehabilitation begins after leaving the hospital. As described by the U. Public Health Service, it is a comprehensive, long-term program including medical evaluation, prescribed exercise, cardiac risk factor modification, education and counseling. Phase II refers to medically supervised programs that typically begin one to three weeks after discharge and provide appropriate electrocardiographic monitoring. Phase III cardiac rehabilitation utilizes a supervised program that encourages exercise and healthy lifestyle and is usually performed at home or in a fitness center with the goal of continuing the risk factor modification and exercise program learned in phase II. Phase IV cardiac rehabilitation is based on an indefinite exercise maintenance program. These programs encourage a commitment to regular exercise and healthy habits for risk factor modification to establish lifelong cardiovascular fitness. Participation within these programs is determined by appropriate risk stratification in order to maximize health care resources and patient benefit. Entry into such programs is based on the demonstrated limitation of functional capacity on exercise stress testing, and the expectation that medically supervised exercise training will improve functional capacity to a clinically significant degree. The exercise test in cardiac rehabilitation is a vital component of the overall rehabilitative process as it provides continuous follow-up in a noninvasive manner and adds information to the overall physical evaluation. In general, testing is performed before entering the cardiac rehabilitation exercise program, and sequentially during the program to provide information on the changes in cardiac status, prognosis, functional capacity, and evidence of training effect. Depending on the degree of debilitation, cardiac patients may or may not require a full or supervised rehabilitation program. The scientific literature

documents that some of the benefits of participation in a cardiac rehabilitation program include decreased symptoms of angina pectoris, dyspnea, and fatigue, and improvement in exercise tolerance, blood lipid levels, and psychosocial well-being, as well as a reduction in weight, cigarette smoking and stress. The efficacy of modification of risk factors in reducing the progression of coronary artery disease and future morbidity and mortality has been established. There are alternative approaches to this typical model. Patients can be classified as low-, moderate- or high-risk for participating in exercise based on a combination of clinical and functional data. The number of recommended supervised exercise sessions varies by risk level: There is limited evidence on the appropriate duration of cardiac rehabilitation. Hammill et al stated that for patients with coronary heart disease, exercise-based cardiac rehabilitation improves survival rate and has beneficial effects on risk factors for coronary artery disease. However, the relationship between the number of sessions attended and long-term outcomes is unknown. They used a Cox proportional hazards model to estimate the relationship between the number of sessions attended and death and myocardial infarction MI at 4 years. The cumulative number of sessions was a time-dependent co-variate. The authors concluded that among Medicare beneficiaries, a strong dose-response relationship existed between the number of cardiac rehabilitation sessions and long-term outcomes. Attending all 36 sessions reimbursed by Medicare was associated with lower risks of death and MI at 4 years compared with attending fewer sessions. Prior and colleagues tested feasibility and effectiveness of 6-month outpatient comprehensive cardiac rehabilitation CCR for secondary prevention after transient ischemic attack or mild, non-disabling stroke. Consecutive consenting subjects having sustained a transient ischemic attack or mild, non-disabling stroke within the previous 12 months mean of These researchers measured 6-month CCR outcomes following a prospective cohort design. Of subjects recruited from January to April , subjects mean age of These investigators obtained favorable, significant intake-to-exit changes in: Compared with intake, 11 more individuals The authors concluded that CCR is feasible and effective for secondary prevention after transient ischemic attack or mild, non-disabling stroke, offering a promising model for vascular protection across chronic disease entities. The authors stated that they know of no similar previous investigation, and are now conducting a randomized trial. Pack et al noted that outpatient CR decreases mortality rates but is under-utilized. Current median time from hospital discharge to enrollment is 35 days. These researchers hypothesized that an appointment within 10 days would improve attendance at CR orientation. At hospital discharge, patients with a non-surgical qualifying diagnosis for CR were randomized to receive a CR orientation appointment either within 10 days early or at 35 days standard. The primary end-point was attendance at CR orientation. Secondary outcome measures were attendance at greater than or equal to 1 exercise session, the total number of exercise sessions attended, completion of CR, and change in exercise training work-load while in CR. The number needed to treat was 5. Safety analysis demonstrated no difference between groups in CR-related adverse events. The authors concluded that early appointments for CR significantly improved attendance at orientation. This simple technique could potentially increase initial CR participation nationwide. In a retrospective cohort study, Beauchamp et al examined if attendance at CR independently predicts all-cause mortality over 14 years and whether there is a dose-response relationship between the proportion of CR sessions attended and long-term mortality. The sample comprised men and women eligible for CR following MI, coronary artery bypass surgery or percutaneous interventions. Participants were tracked 4 months after hospital discharge to ascertain CR attendance status. Main outcome measure was all-cause mortality at 14 years ascertained through linkage to the Australian National Death Index. There were few significant differences between non-attenders and attenders. The authors concluded that this study provided further evidence for the long-term benefits of CR in a contemporary, heterogeneous population. While a dose-response relationship may exist between the number of sessions attended and long-term mortality, this relationship does not occur independently of smoking differences. They stated that CR practitioners should encourage smokers to attend CR and provide support for smoking cessation. Stable patients are defined as patients who have not had recent less than or equal to 6 weeks or planned less than or equal to 6 months major cardiovascular hospitalizations or procedures. Shibata

et al stated that recent studies have suggested the presence of cardiac atrophy as a key component of the pathogenesis of the postural orthostatic tachycardia syndrome POTS , similar to physical deconditioning. It has also been shown that exercise intolerance is associated with a reduced stroke volume SV in POTS, and that the high heart rate observed at rest and during exercise in these patients is due to this low SV. A total of 19 18 women POTS patients completed a 3 month training program. Cardiovascular responses during maximal exercise testing were assessed in the upright position before and after training. Resting left ventricular diastolic function was evaluated by Doppler echocardiography. Results were compared with those of 10 well-matched healthy sedentary controls. There were no changes in any Doppler index after training. The authors concluded that these results suggested that short-term exercise training improves physical fitness and cardiovascular responses during exercise in patients with POTS. Although it can be argued that a structured exercise program for physical reconditioning may be beneficial for patients with POTS, it is unclear there is a need for a supervised cardiac rehabilitation program. Gaalema et al noted that continued smoking after a cardiac event greatly increases mortality risk. Smoking cessation and participation in CR are effective in reducing morbidity and mortality. However, these 2 behaviors may interact; those who smoke may be less likely to access or complete CR. These researchers explored the association between smoking status and CR referral, attendance, and adherence. They carried out a systematic literature search examining associations between smoking status and CR referral, attendance and completion in peer-reviewed studies published through July 1, For inclusion, studies had to report data on outpatient CR referral, attendance or completion rates and smoking status had to be considered as a variable associated with these outcomes. A total of 56 studies met inclusion criteria. A history of smoking was associated with an increased likelihood of referral to CR. However, smoking status also predicted not attending CR and was a strong predictor of CR drop-out. The authors concluded that continued smoking after a cardiac event predicts lack of attendance in, and completion of CR. The issue of smoking following a coronary event deserves renewed attention. Huang et al examined the effectiveness of telehealth intervention-delivered CR compared with center-based supervised CR. Existing randomized controlled trials RCTs , reviews, relevant conference lists and gray literature were checked. Randomized controlled trials that compared telehealth intervention delivered CR with traditional center-based supervised CR in adults with coronary artery disease CAD were included. Two reviewers selected studies and extracted data independently. Main clinical outcomes including clinical events, modifiable risk factors or other end-points were measured. A total of 15 articles reporting 9 trials were reviewed, most of which recruited patients with MI or re-vascularization. No statistically significant difference was found between telehealth interventions delivered and center-based supervised CR in exercise capacity standardized mean difference SMD The authors concluded that telehealth intervention-delivered CR does not have significantly inferior outcomes compared to center-based supervised program in low-to-moderate risk CAD patients. Telehealth intervention offers an alternative deliver model of CR for individuals less able to access center-based CR. Choices should reflect preferences, anticipation, risk profile, funding, and accessibility to health service. In a Cochrane review, Taylor et al compared the effect of home-based and supervised center-based CR on mortality and morbidity, health-related quality of life, and modifiable cardiac risk factors in patients with heart disease.

Chapter 5 : Cardiac Rehabilitation - Medical Clinical Policy Bulletins | Aetna

Competency development stages Throughout the cardiac nurse's career, skills and knowledge are continually developed. It follows that the depth of understanding and practice then differs.

This article has been cited by other articles in PMC. This guideline can be considered an addition to the Dutch Multidisciplinary CR guideline, as it includes several novel topics. Methods A systematic literature search was performed to formulate conclusions on the efficacy of exercise-based interventions during all CR phases in patients with CHD. In case of insufficient scientific evidence, recommendations were based on expert opinion. This guideline comprised a structured approach including assessment, treatment and evaluation. Results Recommendations for exercise-based CR were formulated covering the following topics: Conclusions There is strong evidence for the effectiveness of exercise-based CR during all phases of CR. The implementation of this guideline in clinical practice needs further evaluation as well as the maintenance of an active lifestyle after supervised rehabilitation. Coronary heart disease, Exercise-based cardiac rehabilitation, Clinical practice Introduction Coronary heart disease CHD is one of the most common causes of mortality in the Netherlands, with mortality rates of in men and for women, in the year [1]. Exercise training constitutes an important part of CR and is usually conducted by physiotherapists PTs. The intervention is aimed at improving exercise capacity and optimising daily physical functioning in relation to individual physical activity limitations and participation restrictions [8]. Also, exercise programs should induce inactive patients to develop and maintain an active lifestyle, and consequently lower their future cardiovascular risk [9]. The importance and the exact content of an adequate CR exercise protocol is not always sufficiently appreciated [10]. Recently, it was reported that among Dutch CR centres, considerable variation exists in methods for determination of exercise intensity, training intensity and volume, and uniformity of physiotherapeutic interventions [11]. Moreover, many international guidelines and position statements are not specifically aimed at the practical application of exercise-based CR [3 â€” 7 , 14]. Therefore, an updated clinical practice guideline on exercise-based CR was developed by the KNGF, describing optimal physiotherapy care during all phases of CR, including assessment, treatment and evaluation. This paper sums up the main conclusion and recommendations. Methods Guideline development This guideline was systematically developed according to the Physiotherapy Guidelines Development in the Netherlands method [15]. The guideline development group GDG consisted of the following disciplines: An external group from relevant disciplines reviewed the draft versions of the guideline. The members of the GDG and the external members did not have any conflicts of interest. Literature search and recommendations A computerised literature search was undertaken in the Cochrane library, Medline, PEDro-database, Cinahl and relevant national and international guidelines of CR [3 â€” 7 , 12 , 14 , 16], using the following keywords: Recommendations for the efficacy of exercise-based CR were based on systematic reviews or meta-analyses, if available completed with more recent random-clinical trials RCT. Only studies with a PEDro score of more than 5 points out of 10 were included.

Chapter 6 : Dose Escalation Methods in Phase I Cancer Clinical Trials

Traditionally, cardiac rehabilitation programs have been classified into 4 phases, phase I to IV, representing a progression from the hospital (phase I) to a medically supervised out-patient program (phases II and III) to a community or home-based setting (phase IV).

LinkedIn Phases of clinical trials A clinical trial is only done when there is good reason to believe that a new test or treatment may improve the care of patients. Before clinical trials, tests and treatments are assessed in preclinical research. Preclinical research is not done with people. It assesses the features of a test or treatment. For example, the research may aim to learn if a device is harmful to living tissue. Another aim may be to learn more about the chemical makeup of a drug. After preclinical research, tests and treatments go through a series of clinical trials. Clinical trials assess if tests or treatments are safe for and work in people. Clinical trials have five phases. The phases are described next using the example of a new drug treatment: Phase 0 Phase 0 trials are the first clinical trials done among people. They aim to learn how a drug is processed in the body and how it affects the body. In these trials, a very small dose of a drug is given to about 10 to 15 people. Phase I Phase I trials aim to find the best dose of a new drug with the fewest side effects. The drug will be tested in a small group of 15 to 30 patients. Doctors start by giving very low doses of the drug to a few patients. Higher doses are given to other patients until side effects become too severe or the desired effect is seen. If a drug is found to be safe enough, it can be tested in a phase II clinical trial. The drug is often tested among patients with a specific type of cancer. Phase II trials are done in larger groups of patients compared to Phase I trials. Often, new combinations of drugs are tested. Patients are closely watched to see if the drug works. However, the new drug is rarely compared to the current standard-of-care drug that is used. If a drug is found to work, it can be tested in a phase III clinical trial. These trials assess the side effects of each drug and which drug works better. Phase III trials enroll or more patients. Often, these trials are randomized. This means that patients are put into a treatment group, called trial arms, by chance. Randomization is needed to make sure that the people in all trial arms are alike. This lets scientists know that the results of the clinical trial are due to the treatment and not differences between the groups. A computer program is often used to randomly assign people to the trial arms. There can be more than two treatment groups in phase III trials. The control group gets the standard-of-care treatment. The other groups get a new treatment. Neither you nor your doctor can choose your group. Every patient in a phase III study is watched closely. The study will be stopped early if the side effects of the new drug are too severe or if one group has much better results. The drug is tested in several hundreds or thousands of patients. This allows for better research on short-lived and long-lasting side effects and safety. For instance, some rare side effects may only be found in large groups of people.