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Research Article

Feasibility Indicators in the Analysis of Quality of Life and Depression/Anxiety Scores in Patients after Myocardial Infarction and Percutaneous Coronary Intervention Under Physiotherapeutic Treatment – Qualitative Study

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Abstract

Purpose: The aim of this study was to examine the feasibility of implementing a study design investigating the effects of physiotherapeutic treatment in the acute myocardial infarction (MI) phase.

Methods: Seventy-seven patients with acute MI who underwent Percutaneous Coronary Intervention (PCI) were asked to participate in the study voluntarily. The MI mobilization plan consisted of three stages; each stage lasted two days, starting with the Percutaneous Coronary Intervention (PCI) day. The patients completed the questionnaires (MacNew Heart Disease Quality of Life Questionnaire and Hospital Anxiety and Depression Scale (HADS-D)) independently on the first day of treatment and the day of discharge. The expected outcome was the study design's feasibility in practice.

Results: Fifty from 72 enrolled patients (69.4%) completed the study. The data collection was successful, no participant had to be excluded. The study was planned for six months, but was extended to 9 months to reach the target sample size (n=50). 72% of the patients have already been encountered in the first stage of MI mobilization plan. The participant's acceptability showed an average of 1.6 (SD 1.0) on a scale of 0-10, lower score indicating higher satisfaction.

Conclusion: The feasibility of the study methods was confirmed with the recruitment, retention rates, and accuracy of data collection, and that of the program with the participant's acceptability.

Introduction

Feasibility studies receive hardly attention in the scientific research field (1), although in some of the studies it would make sense to assess the feasibility of methods and procedures (2–5).

The UK National Institute for Health Research (NIHR (6,7)) developed a definition of feasibility studies: "Feasibility studies are pieces of research done before a main study in order to answer the question ´can this study be done?´ They are used to estimate important parameters that are needed to design the main study" (8).

Pfledderer et al. (9) advocates carrying out a feasibility study, arguing that: " …feasibility studies play an essential role in the process of conducting larger scale clinical trials by providing information about the potential efficacy and feasibility of an intervention and addressing uncertainties around conducting a larger scale study."

Bowen et al. (10) describe the rational for performing a feasibility study

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with the following key areas and possible outcomes: implementation (success or failure of execution), practicality (factors affecting implementation ease or difficulty), integration (perceived fit with infrastructure), expansion (costs to organization and policy bodies), acceptability (satisfaction), demand (perceived positive or negative effects on organization), limited efficacy (effect size estimation) and adaptation (degree to which similar outcomes are obtained in new format). Rogan et al. (11) emphasizes that it is important to establish the criteria of success and present them as the primary endpoint such as: process (determining recruitment rates, retention rates etc.), resources (assessing time and budget problems), management (human and data optimization problems) and scientific (estimation of treatment effect and safety).

Purpose: The main goal of this study was to probe the feasibility of implementing a randomized control study that examines the effectiveness of physiotherapy in the acute MI phase (according to NIHR (7) feasibility studies may or may not be randomized). The questions to be investigated by the target study are whether a difference between the therapy group (daily physiotherapy, education with MI flyer and 6-minute walk test (6 MWT) on the day of discharge) and the control group (hand out MI flyers without personal education or daily physiotherapy and 6 MWT on the day of discharge) on the quality of life and in functional capacity exists. The period of our investigation is within the first and most vital phase of cardiac rehabilitation (12). Haykowsky et al. (13) conducted a meta-analysis and found that delaying the start of training leads to a poorer baseline situation in terms of left ventricular function. This confirms the need for daily therapy immediately after MI (14,15). Ryan et al. (16) described that the early start of exercise training and education about the rules of conduct in everyday life has a stress-reducing and behavior-modifying effect, leading to a better quality-of-life score. Increasing the quality of life of MI patients is a general goal of medical measures. The health-related quality of life (HRQoL) is an essential assessment parameter for the effectiveness of therapeutic services in clinical-cardiological research (17,18).

Material and methods

Participants

Patients with acute MI (NSTEMI, non-ST-elevation myocardial infarction; AW STEMI, anterior wall ST-elevation myocardial infarction; PW STEMI, posterior wall ST-elevation myocardial infarction) with PCI took part in the study voluntarily. The inclusion criteria were acute MI with PCI. The exclusion criteria were MI with conservative therapy, palliative patients, language barrier, patients with dementia or immobility, and isolated patients with acute infection. Ethical approval was obtained from the Ethics Committee of the Hospital Kreiskliniken Reutlingen GmbH before recruitment. The participants were informed that they could withdraw from the study at any time. All the enrolled patients signed an informed consent before participation.

Methods

The study methods were originally described elsewhere (19). The methods description partly reproduces their wording, see also supplementary materials. Briefly, the physiotherapeutic treatment in phase I in Kreiskliniken Reutlingen GmbH, Germany, includes the dose increase in cardiovascular fitness according to the myocardial infarction mobilization plan based on the Heidelberger model (20) and the education about the rules of conduct in everyday life with the help of a myocardial infarction flyer (Table 1).

The German version of the MacNew (MacNew Heart Disease Quality of Life Questionnaire, see supplementary materials) and the HADS-D (Hospital Anxiety and Depression Scale, see supplementary materials) were used to examine the quality of life, anxiety, and depression scores. The necessary permission for using the questionnaires was granted via license fees. The retrospective questionnaires were filled out independently on the first day of treatment and the day of discharge. The first time, the patients had to think about the week preceding coronary angiography and, on the day of discharge, about the week of hospitalization after PCI. They filled out the questionnaires accordingly (Table 2).

Table 1: *The myocardial infarction mobilization plan*

Stage I (Day 1*+2)	**Stage II (Day 3+4)**	**Stage III (Day 5+6)**
Education with Flyer	Discuss the questions	Discuss the questions
Study own heart rate measure	Own heart rate measure control	-
Bed or chair-exercises with exercise/relaxation 1:2	Chair-exercises with exercise/ relaxation 1:1	Chair-exercises with exercise/ relaxation 2:1
Walking into the room	Walking on the corridor	Stair climbing
Limitation of the heart rate is 10 more than the resting heart rate	Limitation of the heart rate is 20 more than the resting heart rate	Limitation of the heart rate is 30 more than the resting heart rate
STOP by discomfort, pulse limit exceeded, systolic pressure value 20> mmHg than at rest, respiratory rate >32 min^{-1}		

**Day 1 is PCI day*

Table 2: *Study protocol.*

Study Protocol	
Physiotherapist specialized in cardiology	**Patient**
MI mobilization plan and education daily. No therapy on weekends.	Day 1 physiotherapy: MacNew and HADS-D filled out independently
Vital parameter measurements (at rest, after chair-exercises, after walking or after climbing stairs, and then at recovery after 3 min)	Discharge day with physiotherapy: MacNew and HADS-D filled out independently

Vital parameter (blood pressure, pulse, respiratory rate and oxygen saturation)

The criteria of success for this study were: recruitment rates, data collection time, potential human optimization problems and acceptability of the program.

Procedure

Physicians at the intensive care unit, intermediate care unit, or cardiology section in Kreiskliniken Reutlingen identified potential participants based on the inclusion criteria and issued prescriptions for in-hospital physiotherapy treatment. A research assistant (physiotherapist working on the above-mentioned sections) conducted the therapy based on the mobilization plan.

Statistical analysis

We use descriptive statistics to present the sample characteristics, including means, standard deviations (SD), and percentages.

Results

Feasibility of the study methods and program:

Seventy-seven persons with acute MI were asked to join the study, and seventy-two initially consented. Five patients (6.5%) declined the participation. There were 50/72 (69.4%) persons who also completed the study. Four (5.6%) patients had to withdraw from the study because an urgent coronary bypass surgery had to be performed. One (1.4%) patient stopped because of the language barrier. Seventeen (23.6%) patients engaged in physiotherapy, but they did not hand in the second questionnaire package for different reasons on the day of discharge.

The data collection by the 50 MI patients was successful. The participants completed their questionnaire (MacNew and HADS-D) to an extent (21,22) that we could use the data, and no one had to be excluded. Physiotherapists documented all vital parameters measured according to the protocol.

Table 3 presents the demographic characteristics of the study participants. The mean age of the patients was 58.4 (SD, 11.3), ranging between 30 and 81 years. More than half of the patients were male (66%), with a diagnosis of NSTEMI (56%), with reduced left ventricular pumping function (52%) and 38% with two vessel coronary heart disease (CHD).

Concerning time management, the study was planned for six months but was extended to 9 months to reach the preliminarily defined sample size (n=50). MI patients spent an average of 6.9 (Standard deviation, SD 1.9) days in the hospital and received an average of 3.6 therapy units (SD 1.1). A therapy unit lasted between 30 minutes and 1 hour, depending on the MI mobilization stages and the interest of the patients.

Regarding the beginning of physiotherapy treatment, 36/50 (72%) patients have already been encountered in stage 1, and 14/50 (28%) persons in stage II, respectively.

The feedback from participants to the question “How satisfied were you with the physiotherapy treatment?” with answer options from 0-10, a lower score indicating higher satisfaction, showed an average of 1.6 (SD 1.0).

Table 3: *Demographic characteristics of the study participants (N=50).*

		N	%			N	%
Diagnosis:	NSTEMI	28	56	Gender	Male	33	66
	AW STEMI	10	20		Female	17	34
	PW STEMI	12	24				
				LV function	Normal	24	48
Age	30-39Y	3	6		Mildly reduced	11	22
	40-49Y	8	16		Moderately reduced	13	26
	50-59Y	14	28		Severely reduced	2	4
	60-69Y	18	36				
	70 Y >	7	14	Coronary Artery Disease	1 Vessel CAD	13	26
					2 Vessel CAD	19	38
					3 Vessel CAD	18	36

Discussion

The feasibility of the study methods was confirmed with the recruitment, retention rates, and accuracy of data collection. The feasibility of the program was confirmed with the participant's acceptability.

The practical part of the program emphasized the importance of team communication and collaboration. The feedback from physiotherapists, physicians, and participants in the study context was essential in identifying possible changes to the program to ensure its successful implementation. However, the proposed changes were at the execution level (e.g. simultaneously with confirming an acute MI diagnosis, physicians should prescribe physiotherapy for eligible patients, preventing delays at the beginning of the physical therapy. Furthermore, at the weekend, it must be ensured that the clinical staff is well informed about the study, and remind the patients in case of discharge on the weekend to submit the completed questionnaires before they leave the hospital). We did not have to modify the design of the program.

The study methods were feasible and effective in reaching our target number of patients. From the 77 eligible patients asked, 50 persons completed the study by the recruitment. This 65% rate is similar to other results in the literature (23). Further, the low rates of missing items by the questionnaire data acquisition (within the permitted normal range (21,22), so that no questionnaire was discarded) confirm that efficient data collection is also feasible.

The extension of the study length from 6 to 9 months for a sample size of 50 patients was related partly to the coronavirus pandemic 2021/2022 and its numerous restrictions and the constantly changing regulations for patients and staff in the hospital.

Another factor that influenced the time management is that patients are also admitted on the weekend. This meant, in our case, that 28% of MI patients became physiotherapy from the second stage of the mobilization plan, depending on the admission time. This issue could only be solved with physiotherapy sessions carried out on weekends. However, this is currently not possible due to financial reasons and missing human resources.

Finally, the evidence of the acceptability of the program was provided by the high level of satisfaction regarding physical therapy. Personal feedback from the patient transmitted from physiotherapists and physicians supports these findings.

Considering the outcomes of this study, we set up the target randomized control study, mentioned in the introduction, with confidence.

Conclusions

The study method based on the investigation of physiotherapeutic treatment effects in the acute myocardial infarction (MI) phase is feasible and acceptable to MI patients

A possibly longer recruitment period must be considered depending on the planned case number

Declarations

Data Availability Statement: The data generated and analyzed in this study are available from the corresponding author upon reasonable request.

Conflict of Interest Statement: The authors declare that they have no conflict of interest.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and Ethical Approvals were obtained from the Ethics Committee of the Hospital Kreiskliniken Reutlingen GmbH, Germany, prior to recruitment.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Author Contribution Statement: Conception of the work: KB. Collection of data: KB, KU. Analysis and interpretation of the data KB. Draft manuscript: KB. Revision of the manuscript: KH. All authors have read and approved the final version of the manuscript. All authors declare that they are responsible for all aspects of the work and they will ensure that issues relating to the accuracy of any part of the work are adequately investigated and resolved.

References

1. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: the what, why and how. BMC Med Res Methodol. 2010 Jan 6;10:1.
2. Teresi JA, Yu X, Stewart AL, Hays RD. Guidelines for Designing and Evaluating Feasibility Pilot Studies. Med Care. 2022 Jan 1;60(1):95–103.
3. Leon AC, Davis LL, Kraemer HC. The Role and Interpretation of Pilot Studies in Clinical Research. J Psychiatr Res. 2011 May;45(5):626–9.
4. In J. Introduction of a pilot study. Korean J Anesthesiol. 2017 Dec;70(6):601–5.
5. Hassan ZA, Schattner P, Mazza D. Doing A Pilot Study: Why Is It Essential? Malays Fam Physician Off J Acad Fam Physicians Malays. 2006 Aug 31;1(2–3):70–3.
6. Additional guidance for applicants including a clinical trial, pilot study or feasibility as part of a personal award application [Internet]. [cited 2024 May 17]. Available from: https://www.nihr.ac.uk/documents/additional-guidance-for-applicants-including-a-clinical-trial-pilot-study-or-feasibility-as-part-of-a-personal-award-application/11702
7. Guidance on applying for feasibility studies [Internet]. [cited 2024 May 17]. Available from: https://www.nihr.ac.uk/documents/guidance-on-applying-for-feasibility-studies/20474
8. Eldridge SM, Lancaster GA, Campbell MJ, Thabane L, Hopewell S, Coleman CL, et al. Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework. PLoS ONE. 2016 Mar 15;11(3):e0150205.
9. Pfledderer CD, von Klinggraeff L, Burkart S, Wolfenden L, Ioannidis JPA, Beets MW. Feasibility indicators in obesity-related behavioral intervention preliminary studies: a historical scoping review. Pilot Feasibility Stud. 2023 Mar 22;9:46.
10. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How We Design Feasibility Studies. Am J Prev Med. 2009 May;36(5):452–7.
11. Rogan S, Karstens S. Verwendung der Begriffe Machbarkeits- bzw. Pilotstudien. physioscience. 2018 Mar;14(01):1–2.
12. Tessler J, Bordoni B. Cardiac Rehabilitation. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 [cited 2023 Aug 12]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK537196/
13. Haykowsky M, Scott J, Esch B, Schopflocher D, Myers J, Paterson I, et al. A meta-analysis of the effects of exercise training on left ventricular remodeling following myocardial infarction: start early and go longer for greatest exercise benefits on remodeling. Trials. 2011 Apr 4;12:92.
14. Zhang YM, Lu Y, Tang Y, Yang D, Wu HF, Bian ZP, et al. The effects of different initiation time of exercise training on left ventricular remodeling and cardiopulmonary rehabilitation in patients with left ventricular dysfunction after myocardial infarction. Disabil Rehabil. 2016;38(3):268–76.
15. Mayrhofer / Krenek | Fallbuch Physiotherapie: Innere Medizin mit Schwerpunkt Kardiologie/Pulmologie [Internet]. [cited 2023 Aug 12]. Available from: https://www.beck-shop.de/mayrhofer-krenek-fallbuch-physiotherapie-innere-medizin-schwerpunkt-kardiologie_pulmologie/product/15477322
16. Ryan TJ, Antman EM, Brooks NH, Califf RM, Hillis LD, Hiratzka LF, et al. 1999 update: ACC/AHA Guidelines for the Management of Patients With Acute Myocardial Infarction: Executive Summary and Recommendations: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Acute Myocardial Infarction). Circulation. 1999 Aug 31;100(9):1016–30.
17. Höfer S, Kullich W, Graninger U, Brandt D, Gassner A, Klicpera M, et al. Cardiac rehabilitation in Austria: short term quality of life improvements in patients with heart disease. Wien Klin Wochenschr. 2006 Dec;118(23–24):744–53.
18. Benzer W, Platter M, Oldridge NB, Schwann H, Machreich K, Kullich W, et al. Short-term patient-reported outcomes after different exercise-based cardiac rehabilitation programmes. Eur J Cardiovasc Prev Rehabil Off J Eur Soc Cardiol Work Groups Epidemiol Prev Card Rehabil Exerc Physiol. 2007 Jun;14(3):441–7.
19. Balla K, Haase KK. CARDIOVASCULAR FITNESS, QUALITY OF LIFE AND DEPRESSION/ANXIETY SCORE IN PATIENTS AFTER MYOCARDIAL INFARCTION AND PERCUTANEOUS CORONARY INTERVENTION UNDER PHYSIOTHERAPEUTIC TREATMENT - OBSERVATIONAL STUDY. Eur J Physiother Rehabil Stud [Internet]. 2024 Mar 12 [cited 2024 Mar 15];4(1). Available from: https://oapub.org/hlt/index.php/EJPRS/article/view/167
20. Physiotherapie in der Inneren Medizin : Hüter-Becker, Antje, Dölken, Mechthild, Göhring, Hannelore, Solodkoff, Christiane von, Solodkoff, Michael. 2004.
21. Herrmann-Lingen C, Buss U, Snaith PR. Deutschsprachige Adaptation der Hospital Anxiety and Depression Scale (HADS) von R.P. Snaith und A.S. Zigmond. 4. aktualisierte Auflage. Bern: hogrefe; 2018. 70 p.
22. Höfer S, Turk-Adawi K, Oldridge N. The MacNew heart disease health-related quality of life questionnaire: Updated reference data for users. Eur J Pers Centered Healthc. 2016 Jun 24;4(1):221–9.
23. Markle-Reid M, Ploeg J, Fisher K, Reimer H, Kaasalainen S, Gafni A, et al. The Aging, Community and Health Research Unit-Community Partnership Program for older adults with type 2 diabetes and multiple chronic conditions: a feasibility study. Pilot Feasibility Stud. 2016;2:24.
24. Dixon T, Lim LLY, Oldridge NB. The MacNew heart disease health-related quality of life instrument: reference data for users. Qual Life Res Int J Qual Life Asp Treat Care Rehabil. 2002 Mar;11(2):173–83.
25. Hinz A, Brähler E. Normative values for the Hospital Anxiety and Depression Scale (HADS) in the general German population. J Psychosom Res. 2011 Aug 1;71(2):74–8.