Research Article

Improving Rehabilitation for Patients with Intermittent Claudication: A Randomized Controlled Trial with a Mixed-Methods Evaluation (The CIPIC Rehab Study)

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ABSTRACT

Aim: This study aimed to explore how qualitative data about rehabilitation for patients with intermittent claudication do provide an enhanced understanding of the quantitative experimental results.

Background: The study was a randomized clinical trial comparing a rehabilitation intervention with usual care. A statistically significant difference between rehabilitation and usual care was found in walking distance, physical activity, quality of life and diet. The findings from the quantitative and qualitative analyses were analysed separately on their own tradition. In this study, mixed methods address whether the qualitative results could help explain the quantitative results and bring forward additional information.

Design: Complex mixed-method intervention design with a convergent questionnaire variant.

Methods: From April 2017- May 2019, patients diagnosed with intermittent claudication were included in a randomized clinical trial (N=118). In addition, qualitative interview informants from the intervention group were sampled from the quantitative study population for a survey (N=43) and focus group interviews (N=10). Interviews were conducted from April 2018-August 2019.

Results: Integrated analyses identified how improvement in walking distance, physical activity, diet and quality of life was affected by team spirit, pedometer, education and fun exercise in a local setting. Quantitative and qualitative findings primarily confirmed and expanded each other; however, two discordant results were also evident.

Conclusion: Our study adds empirical evidence regarding how a mixed-methods study can be used to obtain a more nuanced understanding of complex healthcare problems. The study provides new knowledge concerning how to set up a rehabilitation programme for patients with intermittent claudication.

Background

The overall aim of the CIPIC Rehab study trial was to test and develop a cardiovascular rehabilitation intervention for patients with intermittent claudication in non-operative management. Multiple randomized clinical trials showing the efficacy of supervised exercise treadmill training (SET), but many patients refuse participation because of the burdensome requirements of SET programmes [1]. The hypothesis was that a specialised rehabilitation programme based on the established cardiac rehabilitation programme would improve maximal walking distance, pain-free walking distance, level of physical activity, healthy diet, quality of life, health behaviour, and reduce anxiety and depression. A mixed-methods design was chosen, combining a randomized controlled trial with qualitative data to assess the effectiveness and evaluation of the rehabilitation intervention from a patient's perspective.

Semi-structured focus group interviews with participants were chosen to evaluate the intervention and explore how it fits the patients in a real-

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world setting to better understand the patients' lived experiences with the rehabilitation programme. A survey with closed-ended and open-ended questions evaluated the intervention and focus groups aimed to explore the knowledge of the rehabilitation needs in more depth [2]. This kind of evaluation within trials explores the implantation, receipt, and setting of the intervention and helps interpret the outcome results. Data were analysed separately for each component to produce sets of findings. The quantitative analyses showed that a cardiovascular rehabilitation programme for patients with intermittent claudication (IC) significantly increased maximal walking distance measured by treadmill walking test and increased physical activity, quality of life (QoL) and healthy diet compared with usual care [3]. Quality of life (QoL) was measured using The Vascular Quality of Life Questionnaire to perceive disease-specific health, and healthy diet was measured by a validated Danish diet questionnaire [4, 5]. Before the treadmill test at 6 and 12 months, a self-reported assessment of general condition in the legs compared to baseline was measured and showed much better condition in the intervention group [6]. Smoking and alcohol consumption was measured by self-reported behaviour [7, 8]. The Hospital Anxiety and Depression Scale (HADS) was used to detect symptoms of anxiety and depression [9]. HADS, alcohol consumption and smoking showed no significant differences between the groups [6].

Findings were reported with P<.05, indicating significance. However, the p-value provides no information about the clinical importance of the findings. The overall findings from the qualitative study highlight how a community-based rehabilitation programme can be supportive and motivate the patients to improve health behaviour and encourage the management of leg pain. Pedometer and a local setting were important motivational factors to keep adherence to the programme. The participants' experiences of the rehabilitation programme were expressed in four themes revealed from the qualitative analysis: i) The shared community, ii) pushing your own limits, iii) spurred by pedometers and somebody waiting, iv) continuing new habits on your own. The participants found the components in the rehabilitation programme meaningful but encountered difficulties in continuing on their own after completion of the programme [6].

Introduction

The CIPIC Rehab study (Cross-sectoral rehabilitation intervention for patients with intermittent claudication) trial was a randomized clinical trial (RCT) that tested a specialised rehabilitation intervention for patients with intermittent claudication in non-operative management versus usual care. The rehabilitation programme was based on the established cardiac rehabilitation programme according to Danish guidelines [10]. A statistically significant difference between rehabilitation and usual care was found in maximal walking distance, physical activity, quality of life and healthy diet [3]. The qualitative part of the study highlights how a community-based rehabilitation programme can be supportive due to support from other patients, a local setting, education, and the use of a pedometer [6]. However, a gap exists because past research has not adequately captured personal views and participants' context when testing outcomes of a community-based cardiovascular rehabilitation intervention. Therefore, there is a need to add qualitative data into a quantitative experimental trial to enrich data about how to set up a rehabilitation programme that fits patients with intermittent claudication. As preplanned findings from the quantitative and qualitative analyses must be integrated to address whether the qualitative results could help explain the quantitative results and bring forward additional information [11, 12].

The Study

I Aims

The purpose of the quantitative component was to investigate walking distance, QoL and changes in health behaviour. The purpose of the qualitative component was to explore the participants' experiences of participation in the rehabilitation intervention. The purpose of the survey was to evaluate the rehabilitation intervention and get information about how the ideal rehabilitation programme should be. The overall aim of this study was to combine the quantitative and qualitative findings to determine additional information about clinical outcomes in The CIPIC Rehab study and to examine the views of participants on the intervention, implementation, components of the intervention and contextual factors that affect the intervention [13].
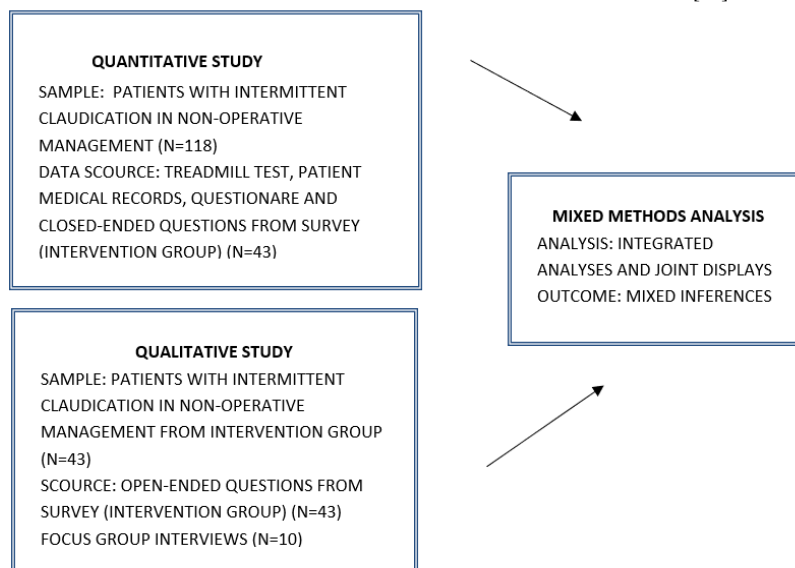

Figure 1: Flow diagram of The CIPIC Rehab Study complex mixed-methods intervention design.
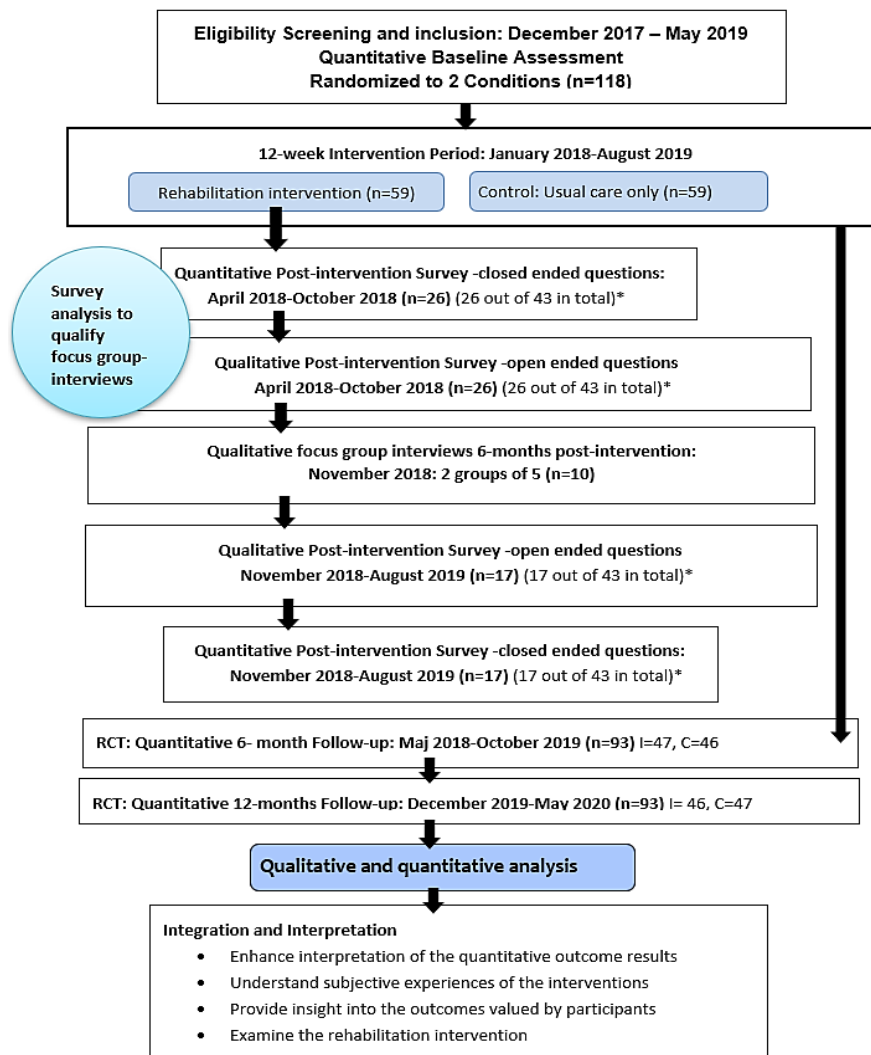
Figure 2: Timeline diagram of The CIPIC Rehab study mixed-methods.
*All participants who completed the intervention were included (n=43) before or after the conducted focus-group interviews.
I: Intervention Group; C: Control Group.

II Design

The present study was designed as a complex mixed-methods intervention design, where the quantitative and qualitative data were collected and analysed on its own tradition to integrate the information within an intervention trial [11]. See flow diagram (Figure 1) and timeline diagram (Figure 2). The quantitative component was designed as an RCT, and the qualitative component had a qualitative exploratory design. Additionally, a convergent questionnaire variant with both open- and close-ended questions was designed [11]. The rationale for this approach is that the quantitative data and their subsequent analysis provide a general understanding of the effects of IC rehabilitation. The qualitative data and their analysis refine and explain the statistical results by exploring participants' views more deeply.

III Quantitative Study

i Sample

From April 2017 to May 2019, patients diagnosed with IC in non-operative management were invited to participate in the RCT study.

Consecutive patients at the Department of Vascular Surgery Outpatient Clinic were screened for inclusion and approached for study participation. The setting was one hospital and one municipal healthcare center in the Capital Region of Denmark. None of the patients had received any interventions before recruitment. Inclusion criteria were conservatively treated patients with newly diagnosed IC using clinical assessment and Ankle Brachial Index Test; age > 18 years; speak and understand Danish; able to provide informed written content; citizens of one of eight municipalities of Greater Copenhagen belonging to the local healthcare center; and expected able to manage transportation and perform the exercise [14]. Exclusion criteria were failure to understand and cooperate according to the trial instructions; comorbidity complicating physical activity and exercise training; and lack of informed content. Based on sample size calculations, 118 patients were included, 59 randomized to the rehabilitation group and 59 to the control group. The trial allocated 118 patients, with 1:1 individual randomization to either intervention or control group. When the informed consent was signed, baseline data were collected, and randomization was conducted. Computer-generated block randomization in four blocks was generated by an independent statistician and delivered in envelopes blinded by the investigator.

Randomization was performed by ongoing inclusion numbers marked on the envelopes.

ii Quantitative Data Collection

Data collection was integrated across methods by constructing the quantitative questionnaires, qualitative semi-structured focus-group interviews, and an evaluating survey. Demographic and clinical data were obtained directly from the patients or the medical records. Maximal walking distance and pain-free walking distance were measured by the standardised treadmill walking test based on a graded protocol: 3.2 km/hour with a 2% increase every 2 minutes [15]. Daily physical activity was measured by the self-reported number of times per week of walking or physical exercise activity of at least 30 min. [16]. Diet was measured by a Danish validated diet questionnaire with a fat and a fish-fruit-green score. To achieve the term "healthy," the score must be at least 75% in each score [5]. Before the treadmill test at 6 and 12 months, a self-reported general condition in the legs compared to baseline was measured. Smoking and alcohol consumption was measured by self-reported behaviour [7, 8]. The Hospital Anxiety and Depression Scale (HADS) was used to detect symptoms of anxiety and depression (scores > 8) [9]. The Vascular Quality of Life Questionnaire (VQ6) was used as a disease-specific instrument to evaluate QoL, where a higher value indicates better health status [4].

iii Quantitative Data Analysis

The quantitative analyses were mainly based on calculations of percentages and means. In addition, some of the analyses were performed using general linear regression models and logistic regression models with adjustment for either sex and age or baseline values, sex, and age. For all analyses, a significance level of 0.05 was used. All analyses were performed using SAS 9.4.

IV Qualitative Study

i Sample

Participants were sampled from the quantitative study population until information power was achieved [17]. To increase the depth of the participant's experiences, two focus-groups interviews were conducted (November 21st, 2018), 6-months post-intervention. The ten participants, who have all been in the same intervention group simultaneously, participated in qualitative focus group interviews as a purposeful sample. All participants were residents in one of the eight local municipalities of Greater Copenhagen that fell under the healthcare center's catchment area.

ii Qualitative Data Collection

Five participants in each focus group knew the vascular nurse from the inclusion in the study and the 2-hour group session. In order to create unity and to secure as safe an environment as possible for the focus group, the participants were matched with others who had been part of the same training team at the same period, and the interviews were held in well-known surroundings in the healthcare center. The number of five participants in each focus group was chosen to ensure each person's opportunity to share insights and observations about the intervention and share their experiences and allow for more in-depth conversation [18].

A semi-structured interview guide for focus-group was used, which included the following themes: experiences with pedometer, logbook, and text messages, experiences with supervised exercise training, experiences with education about IC and healthy diet, experiences with barriers, support, and motivation, experiences of participating in rehabilitation, perception of knowledge about IC, perceptions of environment and togetherness with similar patients.

iii Qualitative Data Analysis

We used a thematic analysis approach to analyse qualitative data, which is a form of patterned recognition allowing for themes to emerge directly using inductive coding after the interviews were audio-recorded and transcribed verbatim. As described by Braun and Clarke, thematic analysis was used as a systematic approach to analyse data from the interviews. This inductive analysis was data-driven in a process that coded the data without trying to fit them into a pre-existing coding frame or any analytical preconceptions [19].

The thematic analysis was carried out in six phases: 1) Familiarizing with the data: Transcribing data, reading and re-reading the data, and noting initial ideas. 2) Generating initial codes: Coding features of interest systematically across the entire data set and collating data codes. 3) Searching for themes: Collating codes into potential themes and relevant themes. 4) Reviewing themes: Checking if the themes worked in relation to the coded extracts and the entire data set and generating a thematic analysis. 5) Defining and naming themes: Ongoing analysis to refine the specifics of each theme and the overall story the analysis tells, generating clear definitions and names for each theme. 6) Producing the report with a selection of vivid, compelling extract examples [19]. Transcripts were reviewed several times for familiarization of data. MS performed the initial coding and searching for themes. Reviewing themes and defining themes were performed by MS and a senior researcher in qualitative expertise, independently of each other. Six categories related to the intervention were initially identified: "team-spirit", "management of the disease", "motivational aspects", "logbook, pedometer and text messages", "rehabilitation exercise", and "suggestion for changes". These six categories were later refined into four categories fitted together from focus group interviews and open-ended questions from the survey: The shared community; pushing your own limits; spurred by pedometers and somebody waiting; and continuing new habits on your own.

Survey

I Sample and Data Collection

In addition to the quantitative RCT data and qualitative focus-group interviews, a supportive evaluation survey component embedded within the RCT design was conducted as a mixed-methods research methodology [20-22]. All 43 patients that completed the intervention were included as a maximum variation sampling. Over a period of sixteen months (April 9th, 2018, to August 5th, 2019), a survey (face-to-face) was collected the day the participant completed the intervention. The first 26 surveys were analysed and used to qualify themes and questions for the focus group interviews (Figure 2). The survey included both multiple-choice questions, closed-ended questions, and open-ended questions. The closed-ended questions in the survey covered the general condition of the patient's legs, the physiotherapist-reported results of the

six-minute walking test and 30-second chair stand test, participation in the exercise sessions, dietician session, nursing session, physical activity, smoking cessation, use and impact of pedometer and logbook. The open-ended part of the survey included the following questions: was a specific part of the rehabilitation particularly meaningful? Do you have any suggestions for the ideal rehabilitation programme? Or other comments? The survey took approximately 15 minutes to complete. It was finished by a dialogue about the design of the personalised motivational text messages if they wanted to receive them (Supplementary Table 1).

II Survey Data Analysis

The results from the open-ended questions were used to confirm the results from the closed-ended questions and to validate the results from the focus group interviews (information power) [11]. The participants' experiences of the rehabilitation programme we revealed from the qualitative focus-group analysis were also found in the surveys: the importance of "togetherness" with other IC patients (the shared community); being pushed forward by professionals (pushing your own limits); motivated by pedometer and the education sessions (spurred by pedometer and health professionals); difficulty doing changes on your own; and a wish to continue with the exercise team (continuing new habits on your own). Mixed methods consist of analytic techniques applied to both the quantitative and the qualitative data as well as the integration of the two forms of data across the quantitative results and the qualitative findings and assessing how the information addresses the mixed-methods questions in the study. Inferences in mixed-methods

research are conclusions or interpretations drawn from the separate quantitative and qualitative strands of the study and across the quantitative and qualitative strands [11].

Mixed-Methods Integration and Analysis

Integration occurred at several levels throughout the study. The integration involved merging the datasets in the parallel database variant and the questionnaire variant by transforming the qualitative results (codes, themes) into quantitative variables (count, constructs, scales) and statistically analysing these emergent variables with the quantitative dataset so that variables arising from the personal experiences of participants could be included in the analysis. A complex mixed-methods intervention design was used at the study design level to collect quantitative and qualitative data within an intervention trial. The primary design was the intervention, and qualitative data was added as a component during (convergent) and after the experiment (explanatory sequential) to enrich the intervention results [11]. In the initial qualitative and quantitative analysis, data were analysed separately. In this study, we consider the survey as both qualitative and quantitative, analysed in this tradition. The integrated analysis is shown as joint displays integrating qualitative and quantitative findings [23]. Integrating at the methods level was achieved through connecting as qualitative informants were sampled from the quantitative study population. Integration of the analysis and reporting was enabled through design by matching questions asked across the questionnaire, survey and semi-structured interview guide (Table 1).

Table 1: Complementary quantitative and qualitative data. The CIPIC Rehab Study.

Quantitative Data Collected Through Questionaries, Patient Medical Records And Survey With Closed-Ended Questions	Qualitative Data Collected Through Semi-Structured Focus Group Interviews And Survey Open-Ended Questions
Walking Distance - Treadmill test, maximal walking distance 6-min walking test - Self-reported walking distance before claudication appears	**Walking Distance** - Experiences with walking - Managing physical activity and burning leg pain
Physical Activity - Level of physical activity/30 min/day - Use of pedometer and logbook 30-second chair stand test	**Physical Activity** - What motivates physical activity? - How do pedometer, logbook impact physical activity
The Vascular Quality Of Life Questionnaire **The Hospital Anxiety And Depression Scale** Condition in the legs compared to baseline	**The Vascular Quality Of Life Questionnaire** **The Hospital Anxiety And Depression Scale** Ability to walk and feeling better mentally
Healthy diet - Nutritional screening - Fat-fish-fruit green score ('hjertekost') - Changes in the score - Bmi and waist measurements	**Healthy diet** - Was advice from the dietician useful? - Impact on changes?
Participation in the intervention **Exercise sessions (physiotherapist)** **Education (vascular nurse)** **Education (dietician)**	**Participation in the intervention** What do you think about the sessions with the physiotherapist, nurse and dietitian?
Components in the rehabilitation programme - Duration - Content - Setting	**Components in the rehabilitation programme** How should the ideal rehabilitation programme be?

Integrating enabled us to match results for a particular topic, merge and weave together qualitative and quantitative findings in content-matched

joint displays, where qualitative and quantitative findings were further analysed into mixed-methods inferences [23]. Senior expertise in mixed-

methods research (DO) worked together with the first author during the process of mixed-methods inference to assess the fit between quantitative and qualitative findings as confirmation, expansion or discordance. Confirmation was achieved if the findings reinforced each other, expansion if the findings diverged or expanded insights of the rehabilitation programme and discordance if the findings were contradictory or in disagreement [24]. Thematic analyses process of the focus group interviews, and open-ended questions survey illustrated by meaning units, condenses meaning units and theme are shown in (Supplementary Table 2).
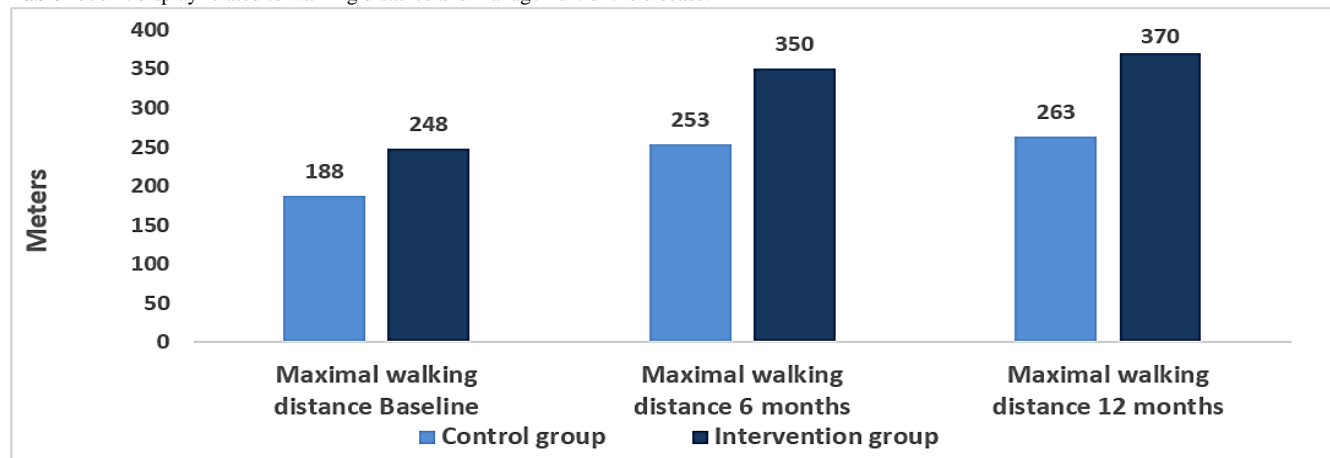
Validity and Reliability

In mixed-methods research, the validity of the quantitative findings and the reliability of the qualitative findings are crucial to the drawn inferences [25]. External validity is high in the RCT design since this population was included following Clinical Practice Guidelines on Diagnosis and Treatment of Peripheral Arterial Diseases [26]. Interpretive and theoretical validity in the qualitative study was ensured by using the participants' own words and including theory on self-efficacy [27]. The reliability of the qualitative study was increased by investor triangulation, enabling the investigators to discuss the findings and agree on the best interpretations. Credibility was further improved using a well-established thematic and systematic qualitative methodology.

Results

Our results are shown as seven joint displays related to walking distance, physical activity, health-related quality of life, healthy diet, participation in the intervention and components of the rehabilitation. Table 2 shows that the qualitative and quantitative findings regarding walking distance confirmed each other. Quantitative evidence finds that walking distance increases significantly in the intervention group, and qualitative findings indicate that the intervention influences walking distance and management of burning leg pain. 6-min walking test improved on average 47 metres between baseline and 12 weeks follow-up. Correlation between patient perception of walking ability and maximal walking distance indicates a weak correlation, which is not statistically significant. Table 3 shows that the qualitative and quantitative findings regarding physical activity confirmed each other. Both datasets indicate that pedometer and logbook are powerful tools to increase daily physical activity with a lasting effect. 95% out of 43 participants in the intervention group used pedometer after 3 months, and 91 % used logbook. At 6 months follow-up, 80 % used pedometer and 61 % used logbook. At 12 months follow up 73 % used pedometer, and 40 % used logbook. Physical activity at least 30/min/day was significantly higher in the intervention group compared to the control group after 6 months and 12 months (P=.010).

Table 2: Joint display related to walking distance and management of the disease.

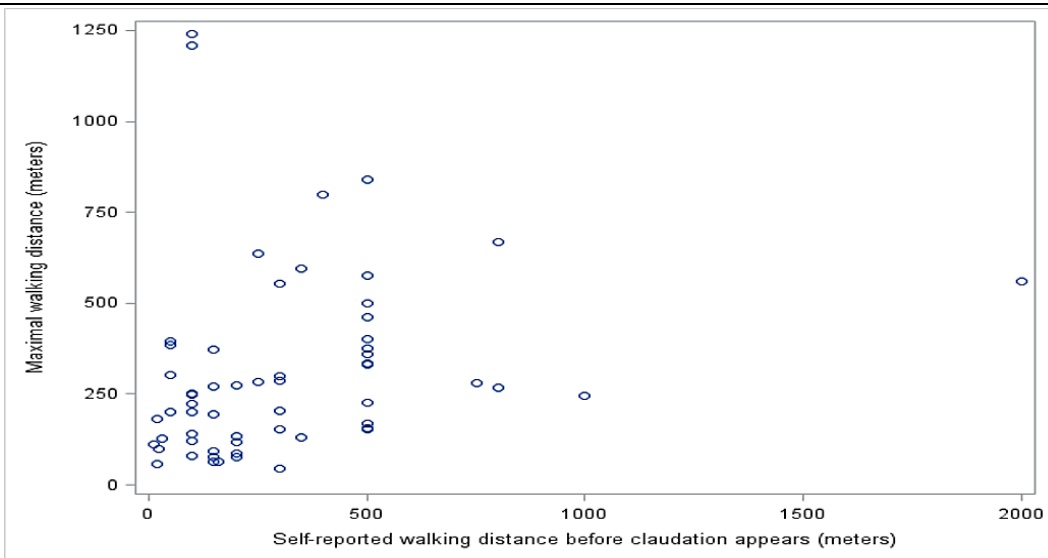Maximum walking distance at baseline, 6 months and 12 months follow-up.

Quantitative Findings:

At 6 months, maximum walking distance increased 37% more in the intervention group compared to the control group (95% CI: 1.10-1.70; P=0.005) (see below). The main effect of intervention was adjusted for sex, age (continuous), and baseline value (time 0). The estimate is the exponential log-transformed mean difference for maximum walking distance, meaning the relative extra meters in the intervention group compared to the control group. At 12-months, walking distance increased 40 % more in the intervention group compared to the control group (95% CI: 1.09;1.80 p=0.008).

6-min walking test: In the intervention group (n=40), 6 min walking test improved on average 47 metres between baseline and 12 weeks follow-up (paired t-test: p<0.001).

30-second chair stand test: In the intervention group (n=39), the Chair stand test improved with 2 stands on average between baseline and 12 weeks follow-up (paired t-test: p<0.001).

To evaluate the association between the patients' perception of walking abilities and the measured maximum walking distance, the correlation between self-reported walking distance before claudication appears and maximum walking distance was estimated (n=59). Both were measured at baseline: The analysis showed a Pearson correlation coefficient of 0.22 (p=0.09), which indicates that the two were weakly correlated at baseline (see below). This correlation was, however, not statistically significant.

Correlation between self-reported walking distance before claudication appears and maximum walking distance.

Qualitative Findings:

The participants experienced significant burning leg pain during physical activity. The pain was described as "now my muscles are burning up" and occurred after physical activity. During the intervention, the participants expressed how they were encouraged and supported by the physiotherapist to exercise despite their leg pain. They explained how they had become convinced that training was an essential aspect of managing their disease and learning about the benefits of exercising despite the pain experienced in pushing their limits and delaying the onset of pain. A patient explained:

"…it hurts right away, but I am walking anyway because I've been told it helps - that it should cure me …so, I try to ignore it…and now I can walk one kilometre without my muscles burning up…" (D)

Mixed-Methods Inferences: Confirmation

Qualitative and quantitative findings regarding walking distance confirmed each other. Quantitative evidence finds that walking distance increases, and qualitative findings indicate that the intervention influences walking distance and management of burning leg pain.

Mixed-Methods Inferences: Discordance

Qualitative and quantitative findings regarding the perception of walking abilities and the measured maximum walking distance indicates that the two were weakly correlated, however not statistically significant.

Table 3: Joint display related to physical activity, pedometer and logbook.

	n (%) at baseline		n (%) at 6 months		n (%) at 12 months	
	Control group (n=59)	Intervention group (n=59)	Control group (n=47)	Intervention group (n=46)	Control group (n=46)	Intervention group (n=47)
Physical activity min.30/min/day	21 (36%)	18 (31%)	15 (32%)	24 (52%)	11 (25%)	24 (52%)
Physical activity 30/min/day was significantly higher in the intervention group after 12 months (P=.010) Control group n=11 (25%) Intervention group n=24 (52%)						
Intervention group	3 months n (%)		6 months n (%)		12 months n (%)	
	n=43		n=49		n=49	
Use of pedometer	41 (95%)		39 (80%)		36 (73%)	
	n=43		n=49		n=47	
Use of logbook	39 (91%)		30 (61%)		19 (40%)	

Quantitative Findings:

Physical activity (self-reported) was significantly higher in the intervention group compared with the usual care group (P=.002). The main part of participants in the intervention group used pedometer at 3 months and at 6 months follow-up, but use decreased to 73 % at 12 months follow-up. The logbook was also used by most participants at 3 months follow-up, and 61% used logbook at 6 months follow-up. At 12 months follow-up, use of logbook declined to 40% of the participants. Among the users of a pedometer, 82% reported that it had "great impact" at 6 months follow-up, and the same was reported by 52% of the users at 12 months follow-up. Among the users of a logbook, 73% reported that it had "great impact" at 6 months follow-up, and 44% of the users reported the same at 12 months follow-up.

Qualitative Findings:

The participants pointed out that they regarded the pedometer as a powerful instrument for motivation and they felt obliged to walk when they saw the numbers on the pedometer. Although almost all the participants used the logbook, for some of them, it was only in the beginning that they found it meaningful when they used it to map their walking route routine. Others used the logbook every day and found it helped to motivate them to go out for a walk and do something about their daily steps goal. Patients explained:

"…I am using the pedometer, looking at it every day… I am completely dependent on that pedometer."(B)

"…at 11.45 p.m. my alarm rings on my phone and I find the logbook and write my steps down…that logbook means everything for me…" (F)

Mixed-Methods Inferences: Confirmation

Qualitative and quantitative findings regarding physical activity and use of pedometer and logbook confirmed each other. Both datasets indicate that pedometer and logbook are powerful tools to increase daily physical activity.

Table 4 shows that the qualitative and quantitative findings regarding Vascular Quality of Life (VQ6) and general condition in the legs confirmed each other, while the quantitative and qualitative findings regarding. The Anxiety and Depression Scale (HADS) and general condition in the legs were discordant. Vascular Quality of Life (VQ6) is a validated disease-specific questionnaire that had a significantly better score in the intervention group compared with the usual care group at 6 and 12 months (P=.020). HADS showed no significant differences between the groups. The questionnaire is validated but not a disease-specific questionnaire. Cut-off values for both HADS-A and HADS-B are 8-10, indicating the possible presence of a mood disorder, and > 11,

indicating the probable presence of a mood disorder. General self-reported condition in the legs compared to baseline showed that at 6 months, 9% in the control group and 28% in the intervention group felt that the condition was much better. At 12 months, 22% in the control group and 36% in the intervention group felt that the condition was much better. Participants who did not improve maximum walking distance and were asked about the general condition in the legs showed that 34% in the control group experienced better condition in the legs at 6 months follow-up. In comparison, 63% in the intervention group experienced the same.

Table 4: Joint display regarding health-related quality of life (VQ6 & HADS) and general condition in the legs.

Quantitative Findings:

Results of linear and logistic mixed models with explorative outcomes measured at 0, 6 and 12 months.

The estimates are the crude proportions, medians or means and proportions with outcomes in intervention and control groups. * N is the number of observations where each person can have up to three observations. † P-value from interaction term between the intervention group and time (0, 6 and 12 months). These were adjusted for sex and age (continuous).

		0 months		6 months		12 months		
	N *	Control	Intervention	Control	Intervention	Control	Intervention	p-value †
Vascular Quality of Life Questionnaire, means	303	14.7	14.6	15.6	17.3	16.0	17.1	0.02
HADS-A $\geq$ 8, %	303	12%	19%	11%	17%	15%	21%	0.96
HADS-D $\geq$ 8, %	303	9%	14%	6%	4%	2%	4%	0.76
General condition in the legs compared to baseline	303	-	-	9%	28%	22%	36%	

Self-reported improvement in the legs among participants that did not improve on their maximum walking distance (<60 metres difference) between baseline and follow-up.

	6 months			12 months		
	Control (n=32)	Intervention (n=19)	Chi^2-p-value	Control (n=26)	Intervention (n=15)	Chi^2-p-value
Self-reported improvement in the legs compared to baseline	34%	63%	0.05	38%	60%	0.18

Quantitative Findings:

Vascular Quality of Life (VQ6) showed a significantly better score in the intervention group compared with the usual care group at 6 and 12 months (P=.020).
A higher value indicates better health status.

The anxiety and depression scale (HADS) showed no significant differences between the groups.
High prevalence of anxiety and depressive disorders among patients with PAD have previously been found. HADS score of 8-10 indicates the possible presence of a mood disorder, and > 11 indicates the probable presence of a mood disorder.

General self-reported condition in the legs compared to baseline showed that at 6 months, 9% in the control group and 28% in the intervention group felt that the condition was much better. At 12 months, 22% in the control group and 36% in the intervention group felt that the condition was much better. It is possible that participants in the intervention group who did not improve on their maximum walking distance still felt that they had improved their general condition in the legs. Therefore, it was evaluated if the proportion of participants with self-reported improvements in the legs at follow-up was larger in the intervention group compared to the control group. This analysis was only performed among participants without improvements in maximum walking distance, and therefore more participants in the control group than in the intervention group were included. The results showed that 34% of the participants in the control group experienced better condition in the legs at 6 months follow-up. In the intervention group, 63% experienced the same. The result was statistically significant (p=0.05). The same trend was seen regarding results on 12 months follow-up, but the result was not statistically significant (p=0.18).

Qualitative Findings:

The participants expressed improvement in well-being and feeling better mentally during the intervention. Knowledge about the disease helped to manage the pain: *"...in my head, it helps a lot to know, now you are making... [collateral circulation] ...now it is good..." (D); "...It occurred to me...when it hurts it is doing good..." (J).* When the intervention ended, they felt it was difficult to exercise on their own, and they felt sad about missing their exercise community:
"...something is missing afterwards. Walking alone is not the same ..." (G); *"I had a mental downturn when it stopped..."* (F).

Mixed-Methods Inferences: Concordance
Qualitative and quantitative findings regarding VQ6, general condition in the legs and feeling better mentally confirmed each other as both indicated that participating in the intervention improved quality of life and general condition in the legs. Knowledge about the disease and feeling better mentally can explain the improvement in general condition in the legs, as some of the patients did not improve walking distance but an improved general condition in the legs.
Mixed-Methods inferences: Discordance
Qualitative and quantitative findings regarding HADS, general condition in the legs, and feeling better mentally were discordant as HADS showed no significant difference between the groups and qualitative findings indicate a difference.

Qualitative and quantitative findings regarding VQ6, general condition in the legs and feeling better mentally confirmed each other as both indicated that participating in the intervention improved quality of life and general condition in the legs. Knowledge about the disease and feeling better mentally can explain the improvement in general condition in the legs, as some of the patients did not improve walking distance but an improved general condition in the legs. The qualitative and quantitative finding regarding HADS, general condition in the legs and feeling better mentally were discordant as HADS showed no significant difference between the groups and qualitative findings indicates that there was a difference.

Table 5 shows that the qualitative and quantitative findings regarding healthy diet expanded each other. Thus, even though only a few of the patients achieved the term "healthy", additional quantitative sub-analyses showed that some changes in diet are possible, while the qualitative findings indicate that the participants could adapt some of the advice about a healthier diet. Table 6 shows that the qualitative and quantitative findings regarding exercise sessions and education sessions expanded each other. Education about the disease and diet is important, but most of all, the exercise sessions. A local setting, variation in exercise, team spirit, having fun, playing, and competition motivates. Per-protocol analyses of the 39 participants who completed at least 70% of the 24 exercise sessions indicate that participating in the intervention depends on what the participants expressed as important motivational factors. Table 7 shows that the qualitative and quantitative findings regarding components of the rehabilitation and the ideal rehabilitation programme confirmed each other. The quantitative findings showed that the main part of participants in the intervention wished to continue the training in a local setting. Qualitative findings showed a strong wish to continue exercise with the team and indicate that the programme fits patients with claudication well, with only a few suggestions to the ideal rehabilitation programme.

Table 5: Joint table regarding a healthy diet.

Quantitative Findings:					
Healthy diet total scores		n (%) value at baseline		n (%) value at 6 months	
		Control group (n=59)	Intervention group (n=59)	Control group (n=47)	Intervention group (n=46)
Achieved the term healthy with a score of at least 75% in the fat-fish-fruit-green score		0 (0%)	1 (2%)	0 (0%)	5 (11%)

Results of linear and logistic mixed models measured at 0, 6 and 12 months.

The estimates are the crude proportions, medians or means and proportions with outcome in intervention and control groups.

Healthy diet changes in scores		0 months		6 months		12 months		
	N *	Control	Intervention	Control	Intervention	Control	Intervention	p-value †
Fat score, mean	303	0.55	0.56	0.55	0.66	0.57	0.71	<0.0001
Fish-fruit-green score, mean	303	0.43	0.43	0.40	0.53	0.41	0.55	<0.0001

* N is the number of observations where each person can have up to three observations. † P-value from interaction term between the intervention group and time (0, 6 and 12 months). These were adjusted for sex and age (continuous).

Quantitative Findings: Healthy diet score showed that only five patients in the intervention group achieved the term "healthy" with a score of at least 75% in the fat score and the fish-fruit-green score. Differences in the fat and fish-fruit-green scores analysed separately showed a significantly higher score in the intervention group at 6 and 12 months (P<0001).
In the intervention group, it was on the items "Intake of nuts" (47%), "Less fat cold cuts" (43%), "Breakfast cereals with more whole grains and fiber" (36%), "Fish for lunch" (36%), and "Meat with less fat" (34%) that the largest proportions had improved their diet between baseline and 12 months follow-up.
Qualitative Findings:
The participants described how they found it useful to learn about healthy food from a dietician:
"Even though I am a chef, I got some good advice from the dietitian, so now I am eating healthier".
Some participants found that their basic knowledge about healthy food was limited and suggested splitting the dietician's sessions in two. If it had been possible to split the sessions, the participants would have had an opportunity to practise some of the advice in real life after a first session and then prepare questions in preparation for a second dietary advice session. Participants also described difficulties in changing their eating habits when they could not feel the difference in their bodies or health right away.

Mixed-Methods Inferences: Expansion
Qualitative and quantitative findings regarding healthy diet expanded each other as the quantitative findings in sub-analyses showed that some changes in diet are possible, and the qualitative findings indicate that the participants could adapt some of the advice about a healthier diet.

Table 6: Joint table regarding participating in the intervention - exercise sessions and education sessions.

Quantitative Findings:
Education session with vascular nurse had 39 participants out of 43 (91%). Education sessions with dietician had 36 participants out of 43 (84%). Only 16 participants out of 43 (37%) accepted the offer of individual dietician guidance.
In the per-protocol analyses, we included 39 patients who completed at least 70% of the 24 exercise sessions and participated in the treadmill follow-up test at 6 months. These findings make estimates and differences stronger in favour of the intervention group with a further 50 metres longer walking distance that increased 45% more in the intervention group compared with the control group (95% CI: 1.17-1.80; P=.001). Improvement at the 6-month follow-up was 400 metres in the intervention group versus 253 metres in the control group.
Qualitative Findings:
All participants expressed that education about the disease and diet is important but highlighted the two talented physiotherapists. They described how a local setting, the great variation in exercise, team spirit, having fun, playing, and competition are motivational factors of participation. They looked forward to what the physiotherapists would come up with next time because it led to different and fun training every time. They described how to exercise with others like themselves, so they do not feel alone, helped them get going. A patient explained: *"...It gives a lot more, more power so you want to do everything when you share it and do it in common."*
Mixed-Methods Inferences: Expansion
Qualitative and quantitative findings regarding participating in the interventions exercise sessions with physiotherapists and education sessions with vascular nurse and dietician expanded each other. Quantitative findings indicated that participating in the intervention depends on what the participants expressed in the qualitative findings of important motivational factors.

Table 7: Joint table regarding components of the rehabilitation and the ideal rehabilitation programme.

Quantitative Findings:
A total of 35 participants out of 43 (81%) wished to continue the training in the healthcare center or participate in a similar programme if possible.
Qualitative Findings:
Interdisciplinary intervention in a local community setting with physiotherapists, vascular nurse and dietician is important. There were only a few new suggestions on how the ideal rehabilitation programme should be. Dietician sessions should be split in two, allowing practising between the sessions and an experienced senior dietician "in eye-level" with the participants. The 35 participants who wished to continue the training after the 12-week intervention were very sad when it ended. They expressed it very clearly: "*I wish so much I could continue the exercise in the team every week all year". "I like the variation in the exercises, and I wanted to continue with the team, even though I had to pay for it.*"
Mixed-Methods Inferences: Confirmation
Qualitative and quantitative findings confirmed each other as both datasets show a strong wish to continue the exercise after 12-weeks, while the qualitative findings indicate that the programme fits patients with claudication well, with only few suggestions to a new programme.

Discussion

This study integrated qualitative and quantitative factors affecting the intervention of a cardiovascular rehabilitation programme for patients with IC. The findings primarily confirmed and further expanded each other. However, two discordant results were also evident. The findings confirmed each other regarding walking distance, physical activity, Vascular Quality of Life (VQ6), general condition in the legs, and components of the rehabilitation and the ideal rehabilitation programme. The qualitative and quantitative findings regarding healthy diet expanded each other. The anxiety and depression scale (HADS) and general condition in the legs were discordant. There was a weak discordant correlation between perception of walking abilities and the measured maximum walking distance. In the CIPIC Rehab study, walking distance increased 37% more in the intervention group compared to the control group. Furthermore, per-protocol analyses showed a further 47 metres longer walking distance that increased 45% more in the intervention group compared with the control group (walking advice group). In per-protocol analyses, mean walking distance increased from 281 metres at baseline to 400 metres at 6-month follow-up in the intervention group and from 188-253 in the control group. The

mean improvement in walking distance was 129 metres in the intervention group and 24 metres in the control group.

Over the past 30 years, treadmill-based SET programs have shown improvement in walking ability assessed by graded treadmill testing, and a meta-analysis of 25 randomized trials showed statistically significant 180 metres (95% CI, 130-238) improvement in maximum walking distance [1]. A multicenter randomized trial by Nicolaï and colleges included 304 patients with IC. Patients were randomized to exercise therapy in the form of "go home and walk" advice (WA) (as the control group in the CIPIC Rehab study), SET (treadmill) or SET (treadmill) with feedback (performance-based accelerometer) provided by a local physiotherapist. The median (interquartile range) change in walking distance between change in walking distance measured by a treadmill at 12 months and baseline in metres was 110 (0-300) in the walking advice group, 310 (145-995) in the SET group, and 360 (173-697) in the SET with feedback group (P<.001 WA vs SET) [28].

The CIPIC Rehab study showed that the 6-min walking test was improved by 47 metres in the intervention group. A study with structured home-based walking exercise intervention found improvement in the 6-min walking test from 41 to 53 metres at 6 months follow-up compared

to a control group. In that study, the intervention improves the 6-minute walking distance more than it improves maximum walking distance at a treadmill test, whereas a supervised treadmill exercise intervention improves treadmill walking more than it improves the 6-minute walking test. Based on these randomized trials, it can be discussed that these results may be related to the fact that a supervised treadmill exercise intervention specifically trains the participants to the treadmill walking measure, whereas a structured intervention focuses on over-ground walking. Clinically meaningful change in the 6-minute walking test distance has been defined: A small change has been defined as 20 m, and a large, meaningful change has been defined as 50 m. However, these findings of meaningful change were not explicitly derived from people with PAD, but results were recognizable in the CIPIC Rehab study.

A systematic review of recruitment for RCT testing SET for patients with PAD concluded that 69% of 1541 eligible participants with PAD refuse participation, and many refuse because of SET programmes' burdensome requirements [29]. The large number of people who find the demands of SET too difficult a community-based cardiovascular rehabilitation programme in a local setting as the CIPIC Rehab study could be a realistic and successful alternative, even though the effect on walking distance is not as high as in a supervised treadmill exercise intervention. The qualitative and quantitative findings regarding physical activity confirmed each other indicating that pedometer and logbook are important tools to increase daily physical activity. The effectiveness of pedometer interventions with goal setting and logbook for steps to promote walking has been documented in systematic and meta-analytic reviews that report such interventions can increase daily steps by approximately 2000 to 2500 steps per day [30]. The utility of pedometers or other wearable accelerometers has not been fully explored in exercise trials in patients with IC but holds promise [1]. A recent systematic review shows some evidence that home-based wearable activity monitors are beneficial for improving walking ability and quality of life in patients with IC [31]. In the CIPIC rehab study, we did not use pedometers to measure the participants' daily steps but only as a motivational tool for the individual patient. The participants' experiences of using a pedometer and how great impact the pedometer had on their daily physical activity can be used in future clinical practice.

The qualitative and quantitative findings regarding Vascular Quality of Life (VQ6) and general condition in the legs confirmed each other, while the quantitative and qualitative findings regarding the anxiety and depression scale (HADS) and general condition in the legs were discordant. It is well known from systematic reviews that there are high prevalence rates of anxiety and depressive disorders among patients with PAD (11-48%) associated with comorbidity, lower-income, loneliness, and health behaviour [32]. An intervention with a specific focus on anxiety and depression might have changed the findings. However, changes in the disease specific VQ6 were significant and confirmed by participants who expressed that they were feeling better mentally. The qualitative and quantitative findings regarding healthy diet expanded each other. Despite the low percentage of "healthy" participants, primarily caused by low intake of vegetables and fruit, some changes in diet are possible. The participants find education about diet important with significant changes on the intake of nuts, cold cuts, whole grains, fish, and fat. It is well known that most patients with IC are overweight, have poor nutrition, with diets particularly high in saturated fat, sodium, and cholesterol, and low in fiber vitamins and minerals [33, 34]. Health behaviour is by nature challenging to change, and research has shown

that despite evidence to support the benefits of dietary modification in risk reduction, adults with IC continue to consume poor diets [35]. The small but significant changes in diet in The CIPIC Rehab study are related to small changes easy to adapt to in everyday life.

Maybe small and easy changes should be a focus-area on future guidance instead of ambitions of fundamental changes in diet. The qualitative and quantitative findings regarding participating in the interventions exercise sessions with physiotherapists and education sessions with vascular nurse and dietician expanded each other. Group sessions and individual counselling were included in the intervention. As a knowledge, interactions with others, and the individual's ability to perform and learn a new skill in the local environment contribute to enhancing participation and motivation [36, 37]. The participants highlighted that team spirit, having fun, playing, and competition were motivational factors indicating that a higher percentage of participation improved the walking distance and expanded motivation for participating. The qualitative and quantitative findings regarding components of the rehabilitation and the ideal rehabilitation programme confirmed each other. The qualitative analysis provided additional information regarding how the rehabilitation intervention may have improved and additional benefits experienced by the participant and programme evaluation.

Limitations

Because the questionnaire variant was used as an add-on to the quantitative instrument, the items generally do not result in a rigorous context-based qualitative data set, also called "mixed methods light" [11]. However, the qualitative database does provide emergent themes and interesting quotes that can be used to validate and embellish the quantitative survey findings. Other researchers like Bryanton and Weeks collected data based on a survey with multiple-choice questions and open-ended questions to gain multiple perspectives [20]. An inherent limitation of qualitative studies is their lack of generalizability. However, the findings are viewed as generalizable for IC patients. Validated scales were used in the quantitative study. The study only included the voices of the participant, leaving out the voice of other relevant parties, such as physiotherapists, dietician or politicians and administrators in the health care sector. Even though all stakeholders could not be included in this mixed-methods study, the voice of the patients was heard. Complex interventions have many potentials "active ingredients" that combine different components in a whole that is more than the sum of its parts. Randomized controlled trials are the most rigorous way to evaluate the effectiveness of interventions, regardless of their complexity. Because of their multifaceted nature in a social context, complex interventions pose methodological challenges [13]. "Good" randomized controlled trials have been defined as those having a high-quality intervention, adequate evaluation of the intervention and its delivery, documentation of external factors that may influence the outcome, and culturally sensitive intervention. The additional costs associated with this would probably be balanced by greater explanatory power and understanding of the generalizability of the intervention [13]. The use of validated instruments and conducting the survey face-to-face improved data collection.

Conclusion

The CIPIC Rehab study provides new empirical knowledge concerning rehabilitation for patients with IC. A combination of the quantitative

results and qualitative findings provided valuable insights for interpreting the trial outcomes and understanding the feasibility of implementing the intervention in clinical practice. The findings of this study offer important guidance for a cardiovascular rehabilitation programme for patients with IC and add empirical evidence regarding how a mixed methods study can be used to obtain an understanding of a complex intervention.

Conflicts of Interest

None.

Ethical Approval

The study complied with the Declaration of Helsinki and was approved by the regional research ethics committee (J. No.:H-17004183) and the Danish Data Protection Agency (J.No.:2012-58-0004).

Consent

Informed written consent was given and signed.

Author Contributions

All authors have agreed on the final version with a substantial contribution to the concept, design, analysis, interpretation, and drafting of the article.

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