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Supplementary Material

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.

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Supplementary Table 1: 3 months' survey: The CIPIC Rehab Study.**3 Months' Survey****Health-Related**

How will you describe your general condition in your legs now, compared to 3 months ago?

- Much better
 Better
 A little bit better
 Almost the same
 A little worse
 Worse
 Much worse

Intervention

Results of the 6 minutes walking test. Distance before intervention _____ Distance after intervention _____

Results of 30-second chair stand test numbers before intervention _____ Numbers after intervention _____

Participation in the sessions

24 exercise sessions with a physiotherapist twice a week:

Participated in all sessions Not participated in all sessions

How many times did you not participate?

Why did you not participate?

Did you participate in the 2-hour session with a vascular nurse? Yes No Did you participate in the 2-hour session with a dietician Yes No Did you receive individual guidance from the dietician? Yes No **Exercise**

What kind of exercise do you want to continue now the rehabilitation is over?

Walks

How often do you walk at least 30 minutes a day?

Number of times per week:

0 2 4 6 >7 1 3 5 7

Are you generally more physically active compared to 3 months ago? (In addition to the intervention training)

Yes No **Smoking**Did you smoke at the inclusion? Do you smoke now? No, I have not been smoking for _____ monthsDo you smoke more now? Less Same quantity as 3 months ago?

How much tobacco do you smoke daily?

(1 cigarette = 1 g, 1 cigar = 4 g, 1 pipe = 3 g, 1 cheroot = 3 g)

 Less than 10 grammes 22-30 grammes 11-21 grammes More than 30 grammes

Have you participated in a smoking cessation course during the last 3 months?

Yes No

Would you be interested in a smoking cessation course, if offered?

Yes No

Did you use any kind of the below medication regularly for more than the latest 3 months?

 Nicotine patch Nicotine inhalator Nicotine gum Nicotine nose spray Nicotine lozenges Varenicilin (Champix) Bupropion (Zyban, Wellbutrin) E- cigarettes Snuff Ingen. None Others Write which

Motivation

How great impact did the pedometer have on the level of your daily physical activity?

- Very great impact
 Some impact
 No impact
 Did not use a pedometer

How great was the impact of the logbook on your daily activity?

- Very great impact
 Some impact
 No impact
 Did not use a pedometer

Do you want to continue using a pedometer? No Yes - What is your daily target? _____

Rehabilitation programme

Is there anything during the course that was particularly meaningful to you? No Yes

If yes, please write what was particularly meaningful to you:

If yes, please write what was particularly meaningful to you:

Have you any suggestions as to an ideal rehabilitation programme? Or other comments?

If you had to decide the ideal course, what would it be?

Do you want to receive text messages on your mobile phone?

No

Yes How often? /time/days?

What kind of text? What will motivate you to, for instance, physical activity, smoking stop, change of diet? Who should be involved, if anybody? - Society, club, training mate, target for the number of steps? Encouragement by smoking desire, visiting XX, etc. What is important?

Supplementary Table 2: Thematic analyses process of open-ended questions survey illustrated by meaning units, condenses meaning units and theme (The CIPIC Rehab Study).

Meaning unit	Condensed meaning unit	Theme
Survey open-ended questions		
Was a specific part of the rehabilitation programme particularly meaningful?		Theme 1 Togetherness with other IC patients (The shared community)*
Team spirit, the music, and fun exercise was the best part.	Team spirit Fun exercise	
I like it all. The fun competition and great variation in the exercises with the whole body	Together with fun competitions and variation	
I also like the sessions with the dietician and nurse.	Education sessions important/new knowledge	
Team spirit and exercise with others like yourself, so you do not feel alone, helps you to get going.	Team spirit helps you to get going Do not feel alone	
Meaning unit	Condensed meaning unit	Theme
Was a specific part of the rehabilitation programme particularly meaningful?		Theme 2 Being pushed forward by professionals (Pushing your own limits)*
It is so important to get pushed forward. I am feeling so much better mentally. Earlier I stopped when my muscles began burning, but now I continue and push myself.	Pushed forward Feeling better mentally	
To be pushed forward. You had to go and follow the timetable	Pushed forward Had to go	
Unity when the exercise is hard to perform.	Pushed forward when it is hard	
I am so happy about it. Using my legs, even though it was hard, but it has to be hard.	Using the legs when it is hard	
Meaning unit	Condensed meaning unit	Theme
Was a specific part of the rehabilitation programme particularly meaningful?		Theme 3 Motivated by pedometer and the education sessions (Spurred by pedometer and somebody waiting)*
I praise the talented physiotherapists. My fitness and well-being are so much better. Pedometer and logbook had a great impact on my daily walking	Learning from the physiotherapists Pedometer motivates daily walking	
I am competing with myself and the pedometer motivates me.	Personal learning and motivation from pedometer	
The physiotherapist spurred you to try a lot of different things, so now I know what kind of exercise I like.	Spurred to do different kinds of exercise	
Now I know, when it hurts it is doing good. Even though I am a chef I got some good advice from the dietitian, so now I am eating healthier.	Learning from nurse session, when it hurts it is doing good. Good advice from dietitian	
Meaning unit	Condensed meaning unit	Theme
Have you any suggestions for the ideal rehabilitation programme? Or other comments?		Theme 4 Difficulty doing changes on your own and a wish to continue with the exercise team (Continuing new habits on your own)*
The exercise should continue as long as you like.	It is difficult to do the exercise alone	
I like the variation in the exercises, and I wanted to continue with the team, even though I had to pay for it.	Variation is highly valued Difficult doing exercise alone and payment is an option.	

I wish so much I could continue the exercise in the team every week all year.	Team exercise is important and it is not the same as doing it alone	
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*(): Themes from focus-group interviews.

Supplementary Table 3: Thematic analyses process of focus group interviews illustrated by meaning units, condenses meaning units and theme (The CIPIC Rehab Study).

Meaning unit	Condensed meaning unit	Theme
		Theme 1 The Shared community (Togetherness with other IC patients)*
"...It gives a lot more, more power so you want to do everything when you share it and do it in common"	The power of sharing and doing it together	
"...Yes, we are all in the same boat"	In the same boat	
"...It was different things we all did every time. For example, we would fill out a pools [betting] coupon, and then we would do 10 exercises in between filling out the coupon..."	Variation in the exercise Fun exercise	
"...we were split into teams and competed. It was childish and so on. It's that kind of thing I think is fun every time..."	Having fun and competition in the team	
Meaning unit	Condensed meaning unit	Theme
		Theme 2 Pushing your own limits (Being pushed forward by professionals)*
"...actually you need to be whipped on"	Pushed forward by physiotherapists and in the team	
"...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..."	Pushing own limits and learn how to manage - nurse education session	
"...when walking on the treadmill, I know when the burning comes, and I slow down the speed instead of stopping"	Learning how to manage and pushing own limits	
"...It is just to get pushed forward"	Pushed forward by physiotherapists	
Meaning unit	Condensed meaning unit	Theme
		Theme 3 Spurred by pedometer and somebody waiting (Motivated by pedometer and the education sessions)*
"...I am using the pedometer, looking at it every day... I am completely dependent on that pedometer"	Motivated by pedometer And using it every day	
"It means something that the physiotherapists stood there waiting for you...then it is not an option not to shown up"	Being expected and spurred by somebody waiting	
"...I look at it (pedometer) to find out how far I am. And my step average is 9000 steps daily"	Using pedometer for daily goals	
"...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..."	Using pedometer and logbook for motivation	
Meaning unit	Condensed meaning unit	Theme
		Theme 4 Continuing new habits on your own (Difficulty doing changes on your own and a wish to continue with the exercise team)*
"...if you don't have the exercise as we did and do it 2-3 times a week and sometimes skipping it, it goes down..."	Exercise goes down when you had to do it alone	
"...something is missing afterwards. Walking alone is not the same ... "	Difficult doing exercise alone -mentally downturn	
I had a mental downturn when it stopped...	Difficulty doing exercise alone	

<p>“...in my head, it helps a lot to know, now you are making...[collateral circulation]...now it is good.....It occurred to me...when it hurts it is doing good...”</p>	<p>Knowledge Patient follows advice from nurse and physiotherapists</p>	
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*(): Themes from survey open-ended questions.