

Determinants for non-attendance to supervised exercise therapy in Dutch patients with intermittent claudication.

Master thesis

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"ONDERGETEKENDE

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SAMENVATTING

Doelstelling: Bij claudicatio intermittens heeft conservatieve behandeling de voorkeur boven invasieve opties. Gesuperviseerde looptherapie (GLT) geeft betere uitkomsten dan niet-gesuperviseerde looptherapie of loopadvies. Echter, therapietrouw is laag. Barrières voor oefentherapie kunnen intrinsiek of extrinsiek zijn. Bij patiënten met claudicatio intermittens zijn extrinsieke barrières voor het volgen van GLT onderzocht. Echter, intrinsieke barrières, zoals demografische gegevens, medische voorgeschiedenis en ziektespecifieke factoren, zijn nog niet onderzocht.

Methode: Het betrof een observationele longitudinale multicenter studie. Patiënten werden door de vaatchirurg geïncludeerd wanneer GLT werd voorgeschreven volgens de richtlijn, en wanneer de Nederlandse taal goed werd begrepen. De vaatchirurg verzamelde basisgegevens. De onderzoeker haalde aanvullende demografische gegevens, medische voorgeschiedenis en ziektespecifieke informatie uit het patiëntendossier. Drie maanden na inclusie werd door middel van een vragenlijst geïnventariseerd of de patiënt nog GLT volgde. Ook bevatte de vragenlijst items over persoonlijke karakteristieken (zoals leeftijd, geslacht, gewicht, lichaamslengte en rookgedrag). Hierna werd de patiënt geklassificeerd als: gestopt met GLT, doorgaan met GLT. Bij de data-analyse zijn allereerst beschrijvende analyses uitgevoerd, welke werden gevolgd door univariate logistische regressie. Een p-waarde ≤ 0.15 werd als relevant beschouwd.

Resultaten: De gegevens van 40 patiënten zijn geanalyseerd. Relevante determinanten voor het stoppen met GLT bleken: body mass index, aangedane been, enkel-arm index in rust en cardiovasculaire aandoeningen in de medische voorgeschiedenis.

Conclusie: De odds voor het stoppen met GLT zijn hoger bij: een hogere body mass index, rechts als aangedane been, een lagere enkel-arm index in rust, en een voorgeschiedenis van cardiovasculaire aandoeningen. Toekomstig onderzoek moet plaatsvinden in een grotere steekproef, om ook multivariate analyses toe te kunnen passen. Daarnaast moeten ook andere intrinsieke barrières worden onderzocht.

Klinische relevantie: Het identificeren van barrières voor het volgen van GLT kan ervoor zorgen dat zorgverleners in kunnen schatten welke patiënten zullen stoppen met GLT. Uiteindelijk kan dit leiden tot strategieën om uitval te voorkomen.

ABSTRACT

Aim: For intermittent claudication conservative treatment is recommended over invasive treatment. The preferred conservative treatment is supervised exercise therapy (SET). However, attendance is low. Barriers for attendance to exercise treatment can be either intrinsic or extrinsic. In patients with intermittent claudication extrinsic barriers for attendance to SET have been studied. However, intrinsic barriers such as demographic data, health status, and disease status have yet to be identified.

Methods: This multicenter observational study had a longitudinal design. The vascular surgeon included patients with intermittent claudication when SET was indicated according to guideline recommendations. Patients needed a good understanding of the Dutch language. The vascular surgeon obtained basic data. Following, the researcher retrieved demographic data, disease status and overall health status from patient records. Three months after inclusion, patients received a survey to determine attendance to SET and asking about personal characteristics (such as age, gender, body height, body weight, smoking habits). Following patients were classified as non-attendant or attendant. For data analysis, descriptive analysis was followed by univariate logistic regression. P-values ≤ 0.15 were considered relevant.

Results: Data of 40 patients has been analyzed. Relevant determinants for non-attendance to SET were body mass index, affected leg, ankle-brachial index in rest, and history with cardiovascular disease.

Conclusion: The odds for non-attendance to SET are higher in patients that have a higher body mass index, are affected in the right leg, have lower ankle-brachial index in rest, and have history with cardiovascular disease. Future research should contain a larger sample size to enable multiple logistic regression. Additionally, other intrinsic barriers should be investigated as well.

Clinical Relevance:

Identification of intrinsic barriers may enable healthcare professionals to determine which patients are more likely to be non-attendant to SET. In the future, healthcare professionals may be enabled to apply strategies to avoid non-attendance.

Keywords: Intermittent claudication, attendance, supervised exercise therapy, SET, health status, disease status, determinants

INTRODUCTION

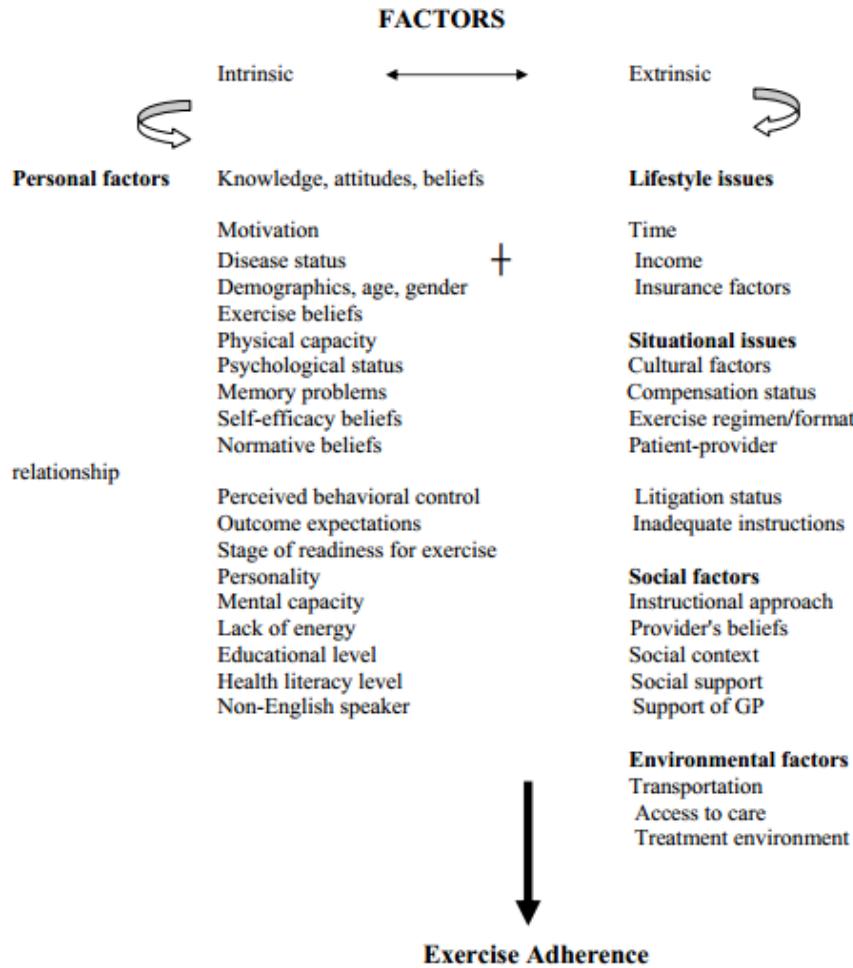
Peripheral arterial disease (PAD) is a chronic cardiovascular disease in which stenoses and/or occlusions of peripheral arteries limit the blood flow to the lower extremities. According to a recent estimate, 202 million people suffer from PAD worldwide.¹ In the Netherlands, the prevalence ranges from 2-7:1000 and increases with age.²

A common symptom of PAD is intermittent claudication (IC) and is characterized by pain and discomfort in the lower limb, which increases during activity and is relieved by rest. The symptoms are caused by reduced arterial blood flow to the muscle fibers. Additionally, patients with IC have an increased risk of coronary heart diseases and cerebrovascular diseases due to general atherosclerosis.³

Guidelines recommend supervised exercise therapy (SET) as initial treatment for all patients with intermittent claudication.⁴ SET is provided by a physical therapist and mainly involves walking therapy, where the subject is told to keep walking until maximal pain.⁵ SET shows better outcome on pain free walking distance and quality of life when compared to unsupervised exercise therapy.⁶⁻⁸ However, despite guideline recommendations many patients with IC are not referred to SET and receive invasive treatment, such as percutaneous transluminal angioplasty (PTA) or open (bypass) surgery.^{9,10} Outcomes between SET and PTA have been studied and show similar results.^{9,11} Recently, data from a Dutch insurance company regarding treatment of patients with IC between 2009-2011 has been studied. The data shows that far fewer patients who received conservative treatment needed surgery within two years (6.4%) when compared to patients who received invasive treatment (35.2%). Additionally, the study shows that conservative treatment is cost-effective compared to invasive treatment.¹⁰

Unfortunately, attendance to SET is low.¹² A German study regarding attendance to a supervised community-based walking exercise program showed a three month attendance of only 32.7% of the subjects.¹³ In order to avoid non-attendance, it is important to identify barriers for attendance. In several populations barriers for attendance to exercise treatment have been studied.^{14,15} Marks studied barriers in a population of patients with osteoarthritis. This study states that barriers can be either intrinsic or extrinsic.¹⁶ A list of the barriers identified in this study can be found in Figure 1. In addition, the barriers found by Marks are similar to those found in an elderly population and in patients with pulmonary disease.^{14,15}

In Germany and the United States studies have been conducted investigating extrinsic barriers for attendance to exercise treatment in a population of patients with IC.^{12,17} Extrinsic barriers were lack of time, high costs, no means of transportation to therapist, and lack of insurance coverage.



*Figure 1: Barriers for attendance to exercise therapy as identified by Marks.*¹⁶

Unfortunately, the two abovementioned studies provide little information on intrinsic barriers for attendance to SET, such as demographics (e.g. age, gender and smoking habits), health status or disease status. However, based on study outcomes in other populations it is likely that intrinsic factors influence attendance to SET in patients with IC as well.

Aim

The aim of this study is to determine which intrinsic factors (regarding demographics, health status and disease status) can be identified as determinants for non-attendance to SET, at the moment of referral, in the Dutch population of patients with IC. Identifying these characteristics may enable healthcare professionals to determine which patients are more likely to be non-attendant to SET. Following, healthcare professionals may be enabled to apply strategies to avoid non-attendance when referring a patient to SET, or when providing SET.

METHODS

Study design

This study is an observational longitudinal multicenter study. It is part of the BeSt study, in which barriers for attendance to SET were studied in a Dutch population of patients with IC. The population consisted of patients with IC who visited their vascular surgeon in the outpatient clinic. The medical research ethics committee (MREC) of the Catharina Hospital Eindhoven stated that the research proposal does not fall under the Medical Research Involving Human Subjects Act.

Setting

The outpatient vascular surgery clinics of seven hospitals participated in this study. The hospitals were situated throughout the Netherlands and were both general hospitals and university medical centers. Inclusion took place between January 1 and March 15, 2014.

Participants

The vascular surgeon included patients at the moment of referral to SET when they met all of the following eligibility criteria:

- Diagnosed with IC by their vascular surgeon
- Eligible for conservative treatment according to current guideline for vascular surgeons.¹⁸
- Willing to sign informed consent

Patients were excluded in case of poor understanding of the Dutch language (both in speaking and reading). Consecutive sampling was used. The patients received verbal information and an informational letter. Additionally, written informed consent was obtained during the appointment. Patients were informed that they could withdraw at any time, without consequences.

Data sources/measurement

After inclusion, the following data were collected by the vascular surgeon: date of inclusion, year of PAD diagnosis, previous treatment for IC, and contact details (e.g. home address and phone number).

Outcome measures

The main outcome measure was attendance to SET. Three months after inclusion patients received a survey inquiring whether they still attended SET (Appendix I). Following, the subject was classified as:

1. Non-attendant: did not start SET, or stopped SET within three months.
2. Attendant: continued SET for at least three months.

Demographic data

Demographic data (age, gender, body weight, body height, smoking habits and pack years)

were obtained through previously mentioned self-administered survey. The body mass index (BMI) was calculated with body height and body weight. Items for the survey were selected based on clinical relevance combined with results from previous research.¹⁴⁻¹⁶

Health and disease status

After referral to SET, the researcher retrieved information regarding health and disease status from the patient records. All relevant comorbidities and diseases in the medical history of the patients were categorized into domains using guidelines from the ICD-9 classification.¹⁹ Additionally disease status was determined by affected leg, localization of occlusion, and the ankle-brachial index (ABI) in rest and after exercise. ABI values ≥ 1.0 were considered normal. Values were considered as borderline when between 0.91-0.99, as pathological when ≤ 0.90 , and outcomes ≤ 0.5 were considered severe.²⁰ For ABI after exercise an ABI decrease of $\geq 20\%$ compared to ABI in rest was considered pathological.²¹

Data analysis

All data analysis were conducted with SPSS 22.0. At first descriptive analyses were conducted for all variables in both the overall group and the subgroups. Available case analysis was used. Mean and standard deviations were calculated for continuous variables, and frequencies were determined for dichotomous variables. Attendance to SET (attendant/ non attendant) was considered the dependent variable. Outcomes for demographic data, health status and disease status were identified as independent variables.

Subsequently, univariate logistic regression analyses were conducted for all of the potential determinants. Some independent variables were not suitable for univariate logistic regression; scores for these variables were either dichotomized or categorized. ABI in rest was dichotomized into 'severe' (≤ 0.5) or 'not severe' (≥ 0.51) and ABI after exercise was dichotomized into 'severe' when ABI after exercise was at least 20% lower compared to ABI in rest. Affected leg and localization of occlusion were categorized. All p-values ≤ 0.15 were considered relevant for further analysis.²²

Finally multivariate logistic regression was conducted, using a forward model. All variables with a p-value ≤ 0.15 in univariate analysis were used to determine which regression model was the best. A forward regression model was used, in which the most relevant determinant is the first to be included, after which subsequently the following most relevant determinants were included in the model.

RESULTS

Participants

Between January 1st and March 15th 2014, 67 patients were included. Figure 2 displays the flow chart of the drop-outs. Ten people were not referred to SET and were therefore excluded from further participation. One person dropped out because of absence of informed consent, and one person withdrew during the phone call with the researcher three months after inclusion. At three month follow-up 55 surveys were sent of which 40 were returned. This results in a response rate of 72.7%.

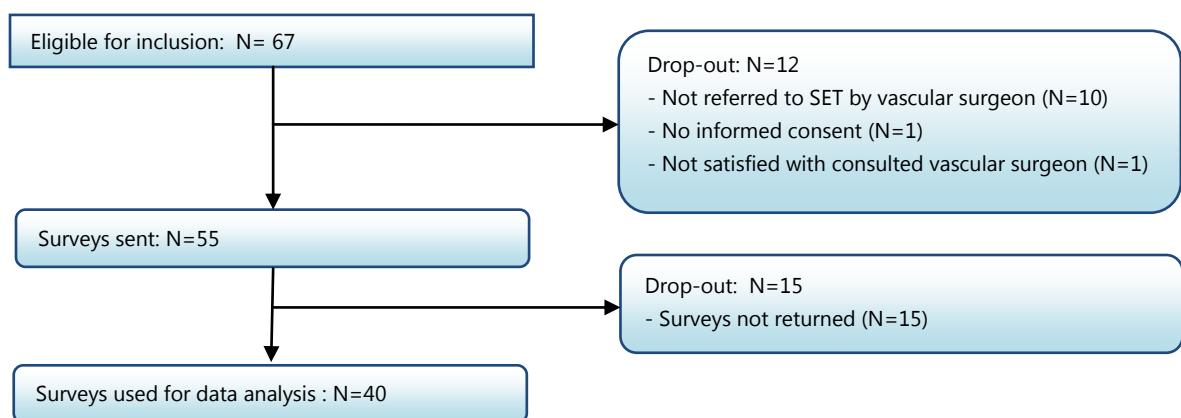


Figure 2: Flowchart of drop-outs

Main results

Descriptive characteristics

At three month follow-up 67.5% of patients still attended SET (N=27). A comparison of the two groups is provided in Table 1. Overall BMI showed an average of 26.9 with a standard deviation of 4.1. In total, 27 of 40 patients were considered overweight with a BMI >25.0. The average BMI was higher in the non-attendant group. Furthermore, frequency of overweight patients was also higher in the non-attendant group (76.9%) compared to the attendant group (63.0%). Forty percent of the patients were smokers with an average of 37.3 pack years for current smokers. The variables 'years since diagnosis' and 'years since smoking cessation' were not normally distributed, but skewed to the right.

In rest, most patients showed 'not-severe' ABI scores (≥ 0.51), after exercise most patients had a 'severe' score, indicating that ABI after exercise had decreased with more than 20% compared to ABI in rest. In total 17.5% of patients had been treated for PAD in the past. The only prior treatment was PTA, none of the patients received SET in the past.

Univariate logistic regression

The outcomes for univariate logistic regression are shown in Table 2. Relevant determinants for non-attendance to SET were BMI, affected leg (significant difference in odds for attendance between left and right leg), ABI in rest, and a history with cardiovascular disease.

Of cardiovascular diseases stroke was the most relevant. All determinants, except BMI, show broad confidence intervals.

Table 1: Descriptive characteristics overall sample, non-attendant group and attendant group.

| Determinants | Overall Mean (SD)/ % | Non-attendant (N=13) Mean (SD)/ % | Attendant (N=27) Mean (SD)/ % |
|---|-------------------------|---|-------------------------------------|
| Gender (% Male) | 65.0 | 54.0 | 70.0 |
| Age (years) | 69.6 (8.8) | 72.1 (7.1) | 68.4 (9.4) |
| BMI(kg/cm2) | 26.9 (4.1) | 28.5 (4.3) | 26.1 (3.8) |
| Years since diagnosis IC | 2.9 (4.7) | 4.3 (6.3) | 2.2 (3.7) |
| % Smokers | 40.0 | 25.0 | 50.0 |
| Pack years smokers | 37.4 (19.0) | 31.5 (20.8) | 39.9 (18.1) |
| Years since smoking cessation | 6.3 (9.9) | 9.8 (12.6) | 4.7 (8.2) |
| Affected leg(s) | | | |
| • % Left | 50.0 | 23.1 | 63.0 |
| • % Right | 25.0 | 46.2 | 14.8 |
| • % Both | 25.0 | 30.7 | 22.2 |
| Localization occlusion | | | |
| • % Iliacal | 10.0 | 0.0 | 14.8 |
| • % Femoral | 20.0 | 7.7 | 25.9 |
| • % Both | 22.5 | 38.5 | 14.8 |
| • % Unknown | 47.5 | 53.8 | 44.4 |
| ABI affected leg(s) rest | 0.65 (0.15) | 0.59 (0.13) | 0.67 (0.16) |
| ABI affected leg(s) after exercise | 0.46 (0.21) | 0.39 (0.18) | 0.50 (0.23) |
| Previous treatment IC | | | |
| • % PTA | 17.5 | 23.1 | 14.8 |
| • % None | 82.5 | 76.9 | 85.2 |
| ICD 240-279 ¹ | 72.5 | 61.5 | 77.8 |
| • % Diabetes mellitus | 32.5 | 30.8 | 33.3 |
| • % Hyperthyroidemia | 2.5 | 0.0 | 3.7 |
| • % Dyslipidemia | 52.5 | 46.2 | 55.6 |
| ICD 390- 429, 439-459 ² | 67.5 | 84.6 | 59.3 |
| • % Hypertension | 60.0 | 76.9 | 51.9 |
| • % Heart failure | 22.5 | 23.1 | 22.2 |
| ➢ ICD 430-438 ³ | 20.0 | 30.8 | 14.8 |
| • % Stroke | 10.0 | 23.1 | 3.7 |
| • % Transient ischaemic attack | 10.0 | 7.7 | 11.1 |
| ICD 490-496 ⁴ | 12.5 | 15.4 | 11.1 |
| • % Chronic obstructive pulmonary disease | 12.5 | 15.4 | 11.1 |
| ICD 710-719 ⁵ | 10.0 | 15.4 | 7.4 |
| • % Osteoarthritis | 7.5 | 7.7 | 7.4 |
| • % Rheumatoid arthritis | 2.5 | 7.7 | 0.0 |
| ICD 720-724 ⁶ | 7.5 | 0.0 | 11.1 |
| • % A-specific low back pain | 7.5 | 0.0 | 11.1 |

S.D. standard deviation

¹ Endocrine, Nutritional And Metabolic Diseases, And Immunity Disorders, ²Diseases Of The Circulatory System,

³Cerebrovascular Disease , ⁴ Chronic Obstructive Pulmonary Disease And Allied Conditions , ⁵ Arthropathies And Related Disorders, ⁶ Dorsopathies

Table 2: Univariate logistic regression

| Determinants | P-value | Odds ratio | 95% confidence interval odds ratio |
|--|--------------|------------|------------------------------------|
| Sex | 0.308 | 2.04 | 0.52-7.99 |
| Age (years) | 0.204 | 1.05 | 0.87-1.14 |
| BMI | 0.097 | 1.16 | 0.97-1.39 |
| Years since diagnosis IC | 0.195 | 1.10 | 0.95-1.26 |
| % smokers | 0.156 | 0.33 | 0.07-1.52 |
| Pack years smokers | 0.221 | 0.98 | 0.94-1.01 |
| Years since cessation smoking | 0.165 | 1.05 | 0.98-1.13 |
| Affected leg(s) (left as reference category): | 0.055 | | |
| • Right | 0.017 | 8.50 | 1.46-49.54 |
| • Both | 0.139 | 3.78 | 0.65-22.02 |
| Localization occlusion | 0.393 | | |
| ABI affected leg(s) rest dichotomized (severe vs. not severe) | 0.067 | 9.38 | 0.85-103.25 |
| ABI affected leg(s) after exercise dichotomized (severe vs. not severe) | 0.718 | 0.68 | 0.08- 5.45 |
| Previous treatment IC | | | |
| • % PTA | 0.522 | 1.73 | 0.32-9.17 |
| Co-morbidity (yes/no) | 0.737 | 1.50 | 0.14-16.00 |
| History with cardiovascular disease | 0.08 | 7.06 | 0.79-62.72 |

Multivariate logistic regression

Overall sample size should have enabled multiple logistic regression with four determinants. However, the number of patients in the non-attendant group was only 13, which is too low given the number of independent variables.²³ Therefore, no multivariate analysis has been conducted.

DISCUSSION

The current study investigated whether intrinsic factors can be determinants for attendance to SET in patients with IC. In univariate logistic regression relevant determinants were found in all three investigated domains: demographic data (BMI), disease status (affected leg, ABI in rest) and health status (history of cardiovascular disease). A comparison of the outcomes for the relevant determinants between groups indicates that people with higher BMI, right leg affected, lower ABI in rest, or a history with cardiovascular disease (hypertension and stroke) have higher odds to be non-attendant to SET. These results suggest that intrinsic factors are indeed relevant for attendance to SET for patients with IC.

The findings of this study are in line with results of research in other populations, which support the argument that intrinsic factors are of influence on exercise attendance.¹⁴⁻¹⁶ This study implies that odds for attendance decrease when patients have a higher BMI. These findings are in line with results of other studies in overweight adult populations.^{24,25} These studies indicate that attendance to exercise programs is limited, and report high drop-out rates. Reported barriers for exercise attendance in overweight people are lack of motivation, low self-efficacy, and inadequate coping skills.²⁶ The results also imply that people with ABI scores ≤ 0.5 are more likely to be non-attendant to therapy. The findings in this population are supported by Galea et al.²⁷ Leg pain caused by the (degree of) occlusion is one of the main barriers for exercise in people with IC. Furthermore, patients with a history of cardiovascular disease, and especially stroke, show decreased odds for attendance to SET. Stroke often leads to decreased walking abilities. Since SET mostly consists of walking therapy, the nature of the treatment could be the cause of non-attendance. Therefore, in patients with walking impairments (not related to IC) other exercise treatment, such as upper limb exercise, should be considered.²⁸⁻³⁰ One remarkable result of this study concerns the increased odds for non-attendance when the right leg is affected, compared to the left leg or both legs. This result has not been reported in other studies. Additional analysis comparing outcomes on other variables with the outcome for the affected leg(s) did not provide rationale for this. It is possible that other (currently unknown) variables could provide an explanation for the difference in odds for attendance between affected leg(s). However, this specific outcome might as well be coincidental.

The attendance rate after three months was 67.5%, which is quite similar to other studies in Dutch patients with IC.^{12,31} However, the attendance rate is much higher when compared with the German study by Müller-Buhl et al. where three month attendance was only 32.7% (percentage of patients who had agreed to attend exercise therapy).¹³ A comparison of demographic characteristics between the current study and the one by Müller-Buhl shows quite similar samples (e.g. age, gender). The most remarkable difference between the studies lies in the amount of patients that did not initiate SET at all. In the study by Müller-Buhl 47% of patients that agreed to attend exercise therapy did not initiate treatment, compared to

15% in the current study. The difference in attendance rate may be explained by the different treatment policies in the two countries. In the Netherlands ClaudicatioNet has developed a care chain, in which all healthcare professionals (e.g. general practitioner, vascular surgeon, and physical therapists) encourage the patient with IC to participate in SET. For German patients with IC there is no care chain like the one that has been developed by ClaudicatioNet.³²

The current study showed a high response rate of 72.7 percent. This high rate could be explained by the fact that all patients received a phone call from the researcher a couple of days before the surveys were sent.³³ During this phone call there was room for withdrawal (N=1) and questions. Additionally, the researcher mentioned that the survey would be sent to the patient that same week.

Some limitations of the current study need to be mentioned. First of all the results of this study may have been biased by inaccurate documentation of patient records during the consult with the vascular surgeon. A study by Paans et al. indicates that accurate documentation of patient records by healthcare professionals in Dutch hospitals is insufficient.³⁴ This may lead to incomplete patient records, for example when co-morbidities are not documented. It is possible that insufficiently documented patient records have lead to distortion of outcomes. Unfortunately, it was not possible to determine whether the documentation of patient records was sufficient.

Secondly, the sample size was too small. The number of patients in the non-attendant group was only 13, which is too small to conduct multivariate logistic regression, given the number of independent variables. This posed a serious risk of bias and therefore, the relevant determinants found in univariate logistic regression could not be put in a multivariate logistic regression model.²³ The small sample size may also provide explanation for the broad confidence intervals that were found, which is indicative for low precision of the calculated odds ratios. Nevertheless, this study has provided relevant parameters for future studies in which these variables may be included in multivariate analysis.

Future research should investigate more barriers for attendance to SET. In other populations patients' health perception has been identified as an important barrier for attendance to exercise treatment.¹⁴⁻¹⁵ Therefore, perceived health status and quality of life should be investigated as well. Additionally, future research should contain larger sample size in order to establish more accurate estimation of odds ratios and to enable multivariate analysis.

CONCLUSION

The results indicate that the odds for non-attendance to SET are higher in patients with IC that have a higher BMI, are affected in the right leg, have lower ABI in rest, and have history with cardiovascular disease (hypertension and stroke). Future research should contain a larger sample size in order to enable multiple logistic regression. Additionally, other variables such as perceived health status and quality of life should be investigated as well.

Identification of barriers for attendance may enable healthcare professionals to determine which patients are more likely to be non-attendant to SET. Following, the healthcare professional can apply strategies to avoid non-attendance when referring a patient to SET, or when providing SET.

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Appendix I: Survey

Geslacht: Man
 Vrouw

Leeftijd: Jaar

Gewicht: Kilogram

Lengte: Centimeter

Vraag 1

Rookt u?

- Nee, en ik heb ik het verleden niet gerookt.
- Nee, ik ben gestopt met roken in(jaartal invullen), ik hebjaar gerookt (aantal jaar invullen)
- Ja, sinds(jaartal invullen)

Onderstaande vragen worden gesteld naar aanleiding van de afspraak die u 3 maanden geleden had met uw arts of verpleegkundig specialist. Naar aanleiding van deze afspraak bent u gevraagd mee te werken aan dit onderzoek.

In onderstaande vragen wordt gesproken over gesuperviseerde looptherapie. Dit betekent looptherapie onder begeleiding van een fysio- of oefentherapeut.

Vraag 2

Heeft de arts of verpleegkundig specialist de mogelijkheid van gesuperviseerde looptherapie met u besproken?

- Nee
- Ja

Vraag 3

Bent u door de arts of verpleegkundig specialist verwezen voor gesuperviseerde looptherapie?

- Nee De vragenlijst stopt hier voor u
- Ja Ga door naar vraag 4

Vraag 4

Bent u gestart met de gesuperviseerde looptherapie bij een fysio- of oefentherapeut?

- Nee
- Ja

Vraag 5

Bent u nog steeds bezig met gesuperviseerde looptherapie bij een fysio- of oefentherapeut?

- Nee *Ga door naar vraag 6*
- Ja *De vragenlijst stopt hier voor u*

Vraag 6

Hoeveel behandelingen heeft u gehad bij de fysio- of oefentherapeut voordat u gestopt bent met gesuperviseerde looptherapie? behandelingen (*aantal behandelingen invullen*)