BMJ Open Quality

Evaluating the implementation of personalised outcomes forecasts to optimise supervised exercise therapy in patients with intermittent claudication in the Netherlands: a multimethods study

Laura H M Marcellis ,[1,2] Anneroos Sinnige ,[3] Katrien M Rutgers,[4,5] Andrew Kittelson ,[6] Steffie Spruijt,[2] Joep A W Teijink ,[7,8] Philip J van der Wees ,[1,9] Thomas J Hoogeboom [1]

To cite: Marcellis LHM, Sinnige A, Rutgers KM, *et al*. Evaluating the implementation of personalised outcomes forecasts to optimise supervised exercise therapy in patients with intermittent claudication in the Netherlands: a multimethods study. *BMJ Open Quality* 2024;**13**:e002594. doi:10.1136/bmjoq-2023-002594

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/bmjoq-2023-002594).

Received 7 September 2023
Accepted 31 January 2024

For numbered affiliations see end of article.

Correspondence to
Dr Thomas J Hoogeboom; Thomas.Hoogeboom@radboudumc.nl

ABSTRACT

Background To support the optimisation of supervised exercise therapy (SET) in patients with intermittent claudication, we developed personalised outcomes forecasts (POFs), which visualise estimated walking distance and quality of life for individual patients. The POFs may enable healthcare professionals, such as physical and exercise therapists, to improve shared decision-making and patient outcomes.

Objectives To assess differences in patient outcomes (functional walking distance, maximal walking distance and health-related quality of life) and the level of shared decision-making before and after the implementation of POFs in the conservative treatment of patients with intermittent claudication.

Methods An interrupted time series design was used to compare preimplementation and postimplementation differences on patient outcomes. Using routinely collected data, differences from baseline to 6 months were compared between patients before and patients after the implementation. To compare levels of shared decision-making, we conducted observations of initial consults within a sample of physical or exercise therapists both before and after the implementation. Audiorecords of observations were scored on shared decision-making using the OPTION-5 instrument.

Results Differences in improvements between patients with whom POFs were discussed (n=317) and patients before the implementation of POFs (n=721) did not reach statistical significance for both functional walking distance (experimental vs. control=+23%, p=0.11) and maximal walking distance (experimental vs. control=+21%, p=0.08). For health-related quality of life, the POFs-informed patients showed a statistically significant greater improvement of 4% (p=0.04). Increased levels of shared decision-making were observed in postimplementation consults (n=20) when compared with preimplementation consults (n=36), as the median OPTION-5 total score showed a statistically significant increase from 45 to 55 points (p=0.01).

Conclusions Integrating POFs into daily practice of SET for patients with intermittent claudication could assist in improving health-related quality of life and enhancing patient involvement. Using POFs did not result in statistically significant different improvements between groups on walking distances.

Trial registration number NL8838.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ To improve personalisation of care, one of the strategies that has been proposed is to monitor a patient's progress and compare this progress with outcomes of similar patients.

⇒ Personalised outcomes forecasts (POFs) visually display estimated walking distance and quality of life for individual patients and were developed to support healthcare professionals in optimising supervised exercise therapy for patients with intermittent claudication.

WHAT THIS STUDY ADDS

⇒ This is the first study to assess differences before and after the implementation of POFs.

⇒ Our findings provide insight into the potential benefits of using POFs on health-related quality of life and shared decision-making.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Integrating POFs into daily practice of supervised exercise therapy for patients with intermittent claudication might assist a selection of therapists in enhancing patient involvement and might support patients to achieve better outcomes.

INTRODUCTION

Evidence-based guidelines primarily recommend supervised exercise therapy (SET) to improve physical functioning and quality of life in patients who suffer from intermittent claudication, the most common symptom of peripheral arterial disease (PAD).[1–5] Although evidence for the short-term benefits of SET is strong,[6 7] there are also

patient-level limitations and barriers that hinder engagement.[8 9] Frequently reported barriers by patients are, for example, comorbid health concerns and the lack of tailored information, guidance and support to achieve walking recommendations.[10–14] These barriers highlight the importance of a personalised approach for exercise therapy in patients with intermittent claudication.

Pursuing a personalised approach shifts the focus away from a traditional paternalistic approach towards one where the healthcare professional includes patient needs, circumstances and personal preferences.[15 16] This approach, also called personalised care or person-centred care, is widely recognised as an essential component of high-quality healthcare due to its positive associations with patient satisfaction, patient behaviour and health status.[15 17 18] One of the commonly proposed strategies to improve personalisation of care is to monitor a patient's progress and compare this progress with outcomes of similar patients.[19–23] In patients with intermittent claudication, healthcare professionals, such as physical and exercise therapists, could use this approach to inform patient expectations, provide tailored and realistic insight into the expected course of therapy and thereby tackle barriers for independent walking such as a lack of belief or certainty that treatment will be effective.[11 14 21]

To support physical and exercise therapists in monitoring walking distance and quality of life in patients with intermittent claudication, we developed personalised outcomes forecasts (POFs) of SET.[24] Similarly to reference charts, POFs provide insight into an individual's personal prognosis by visualising the estimated walking distance and quality of life over the treatment trajectory. The estimates are created using historical outcomes data of patients similar to the patient of interest.[24] By informing patients of the expected course and outcome of therapy, POFs may help therapists to tailor care to the needs of the individual and thereby potentially improve patient outcomes.[25] Moreover, we expect that POFs could enable therapists to improve patient engagement and shared decision-making (SDM).[21 26] The latter is noteworthy since the use of SDM is limited among physical therapists while it is considered a cornerstone of personalised care.[27–31]

The primary research objective (RO1) of our study was to assess differences in patient outcomes (ie, functional walking distance (FWD), maximal walking distance (MWD) and health-related quality of life (HRQoL)) before and after the implementation of POFs in the conservative treatment of patients with intermittent claudication. The secondary RO (RO2) was to assess differences in the level of SDM before and after the implementation of POFs at the start of the conservative treatment of patients with intermittent claudication.

METHODS

Design and participants

We used a multimethod design in which the effect of using POFs in practice was assessed quantitatively by two approaches: (1) examine differences in patient-level outcomes (walking distance and quality of life) before and after the implementation and (2) assess the level of therapist-patient decision-making via observations of clinical interactions.[32 33] The POFs were implemented among physical and exercise therapists affiliated with 'Chronic CareNet', a Dutch nationwide network of specialised therapists providing community-based SET and lifestyle counselling to patients with non-communicable diseases like intermittent claudication.[34] The study was conducted in the Netherlands from August 2019 to November 2021 ('Netherlands Trial Register' number: NL8838), and the study protocol has been described previously.[35] The RECORD checklist was used as a guide in the reporting of this study.[36]

For RO1, the evaluation of patient outcomes, we used an interrupted time series design wherein the POFs were implemented at the level of the therapist (see figure 1).[37 38] Using this design, the implementation followed a sequential approach in four clusters of therapists—based on geographical region—at equal time intervals of 1 month. Data collection for all clusters was divided into a 12-month control period (preimplementation data), a 1-month implementation period and a 12-month experimental

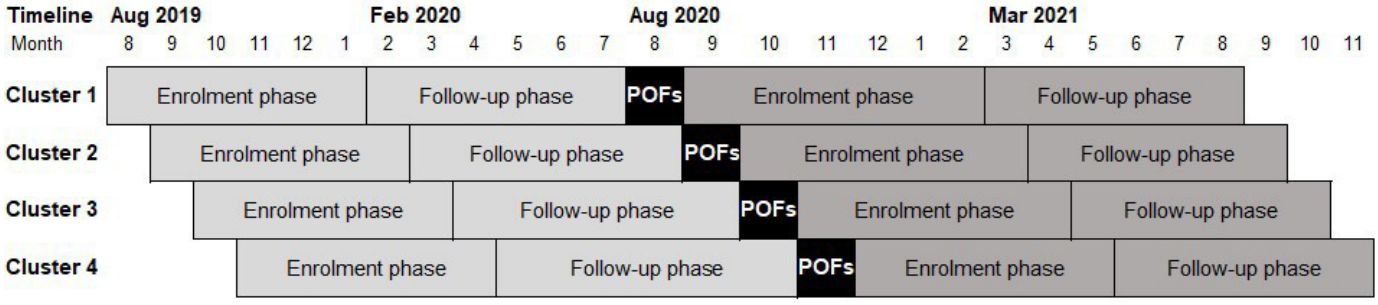

Figure 1 Visual depiction of the timeline of the evaluation of patient outcomes (primary research objective). The different study phases for each cluster are shown: control period (light grey), implementation period of the personalised outcomes forecasts (POFs) (black) and experimental period (dark grey). Enrolled patients were measured at baseline (T0) and 6 months after enrolment (T1).

period (postimplementation data). In both the control and experimental period, the first 6 months comprised the enrolment phase in which baseline measurements (T0) of every newly referred patient with intermittent claudication were collected. Months 7–12 comprised the follow-up phase in which follow-up measurements (T1), 6 months after baseline measurements, were collected. This design allowed us to segregate patients into either the control period (ie, no access to POFs) or the experimental period (ie, therapists were provided access to POFs). For RO2, the evaluation of SDM, we conducted a pre–post test design using audiorecorded observations parallel to the interrupted time series design.

Evaluation of patient outcomes (RO1)

Patient outcome measures used to assess differences before and after the use of the POFs were FWD, MWD and HRQoL and were measured by cluster. Outcomes measurements were collected as part of routine data collection and based on existing quality criteria of Chronic CareNet.[34] All eligible patients were referred to a therapist affiliated with Chronic CareNet, based on a nationwide, community-based approach and provided consent for the use of their clinical data. Patients were excluded if no complete data (baseline and follow-up) were available for one of the three patient outcome measures.

Evaluation of SDM (RO2)

To assess differences in the level of SDM, we conducted audiorecorded observations of therapist and patient conversations at the start of the treatment. Observations were conducted during both the control period (preobservations, without discussion of the POFs) and the experimental period (postobservations, with discussion of the POFs). The level of SDM was measured by scoring the audiorecords using the Dutch version of the validated Observer OPTION 5 scale.[39 40] Preobservations were collected 1–4 months before the implementation of the POFs. Postobservations (with newly referred patients) were collected 7–10 months after the implementation, allowing therapists time to gain experience in using the POFs.

A random subgroup of therapists was invited by email and phone to participate. All therapists who received a new referral for a patient with intermittent claudication during the control period were eligible to participate. Therapists were eligible to participate during the experimental period if they (1) participated during the control period, (2) completed two online e-learnings on the use of the POFs, (3) practiced using the POFs with at least one patient and (4) received a new referral for a patient with intermittent claudication. All referred patients were eligible to participate, unless they were unable to communicate in Dutch.

Implementation of the POFs

During the 1-month implementation period in each study cluster, the POFs were implemented by making them available online for the therapists within a web-based tool (see online supplemental appendix 1 for an example). The POFs could be used in clinical practice in different ways. For example, therapists could discuss patient expectations and promote adherence to exercise therapy at the start of the treatment, or they could monitor progress in therapy results to detect treatment success and opportunities for improvement.[24]

To support therapists in using the POFs, three accredited e-learnings (1.5 hours each) were made freely available: (1) a basic training containing all the necessary information to start using the POFs and (2) two separate in-depth e-learnings to increase knowledge on discussing the POFs with the patient. Completing the basic training was a requirement to start using the POFs in daily practice. Both the POFs and the e-learnings were developed based on feedback from daily practice, and the first use of both the POFs and the basic training were investigated in a pilot study led by two MSc physical therapists who served as knowledge brokers between practice and research.

Therapists were not required to start using the POFs, but they were encouraged to use them to augment their clinical decision-making via direct and indirect channels (ie, online webinars, newsletters, reminder emails). For therapists with additional questions, daily support was available via email or phone.

Data collection

Evaluation of patient outcomes (RO1)

Differences in patients' FWD, MWD and HRQoL between baseline (T0) and 6 months follow-up (T1) were compared between patients included in the control and experimental period. Therapists affiliated with Chronic CareNet participate in routine data collection from electronic health records through the Chronic CareNet Quality system.[34] During the control period, data of patients with intermittent claudication were exclusively collected via this system's database. Patients with intermittent claudication were identified based on the Dutch Diagnostic Coding System for Paramedical Care list. To account for the not detectable use of the POFs in Quality system data, experimental period data were additionally collected via the database of the web-based tool of the POFs (ie, data from all episodes of patients with intermittent claudication in which the POFs were used).

FWD and MWD were measured by therapists as part of daily practice, using a reliable and valid standardised treadmill test based on the Gardner-Skinner protocol, which is recommended by the Dutch physical therapy guideline on intermittent claudication.[4 41 42] FWD was defined as the distance (metres) at which a patient would prefer to stop walking in daily life and MWD as the distance (metres) at which a patient was forced to stop walking due to intolerable claudication pain. The maximal distance patients can walk following the Gardner-Skinner protocol is 2200 metres.[41]

HRQoL was measured by therapists as part of daily practice using the disease-specific Vascular Quality of Life

Questionnaire-6 (VascuQol-6), which has been recommended as the preferred questionnaire to measure quality of life in patients with PAD.[43–45] The VascuQol-6 score ranges from 6 to 24, with a higher score representing a better quality of life.[45]

Evaluation of SDM (RO2)

For both preobservations and postobservations, therapists were observed online during one of the first sessions of the treatment. Observations were audiorecorded using Microsoft Teams when both the therapist and patient provided specific informed consent. After each observation, therapists completed a short questionnaire concerning demographic characteristics of themselves and their patients.

The OPTION-5 was used to assess SDM and consists of 5 items: presenting options (item 1), forming a partnership (item 2), informing about options (item 3), eliciting patient preferences (item 4) and integrating patient preferences (item 5). For each observation, each item was scored on a 5-point Likert scale from 0 (no effort) to 4 (exemplary effort). Item scores were summed and multiplied by 5 so that the total score was between 0 and 100.[46]

A team of three pairs of raters (JH and MH, LB and TB, CB and KMR) scored the observations on the level of SDM regarding treatment goals and treatment plan. After completing a calibration stage to reach interobserver agreement (intraclass correlation coefficient (two-way mixed effects model, absolute agreement, single-measure[47]) of 0.81, 95% CI 0.36 to 0.89), observations were divided between the pairs of raters. Within a pair, each observation was first scored individually, after which a consensus score was determined. Couple JH and MH assessed 19 observations, LB and TB assessed 19 observations, CB and KMR assessed 6 observations and 12 observations were assessed by all raters. To maintain interobserver agreement, a rating protocol (available on request) was used to guide the scoring process.

Statistical analysis and sample size

Descriptive statistics were calculated for therapist and patient characteristics. A difference of $p<0.05$ was considered statistically significant. Data were analysed using IBM SPSS Statistics for Windows V.28.0 and STATA software V.17.0.

Evaluation of patient outcomes (RO1)

To evaluate the change in patient outcomes following the implementation of POFs, we performed a primary analysis using the per-protocol principle, and a sensitivity analysis using the intention-to-treat principle. In the per-protocol analysis, we used data from the web-based POFs tool for the experimental period, to ensure that POFs were generated for all included patient cases. For the control period, we used data from the Chronic CareNet Quality system. In the intention-to-treat analysis, we allowed all possible data to contribute by using data from the Chronic CareNet Quality system for both the control and experimental period, to permit incorporation of patient cases for which POFs may not have been used in practice. All data were analysed using complete case analysis. Complete cases were identified and implausible values were removed (ie, values that were beyond the range of possible values) before conducting the analysis.

A pooled meta-analysis was used for both the primary and sensitivity analysis to compare mean differences in FWD, MWD and HRQoL within each cluster between control and experimental period data. Data were analysed as per cent change ((T1–T0)/T0×100) from baseline to 6 months follow-up. We decided a relative scale (ie, percent change) was more appropriate, given the wide range of baseline measurements. In each cluster, 6 time points (months) were defined before the implementation (control period; M0–M5) and after the implementation (experimental period; M6–M11). Each time point represented the median change of all enrolled patients who completed the 6 months follow-up at that specific month. The median, a robust measure to reduce estimation bias, was used to better deal with outliers due to skewed data.[48] To obtain the mean differences and SEs per cluster, an independent-samples t-test was used for FWD, MWD and HRQoL by comparing the mean of the medians of M0–M5 with the mean of the medians of M6–M11. Subsequently, we performed a pooled meta-analysis (fixed effects) with the mean differences and standard errors of each cluster.

A priori, we expected that approximately 7500 patients would be treated during the control period. We expected that 50% of the therapists would start using the POFs. Therefore, we expected that 3750 patients with whom the POFs were discussed would be treated during the experimental period.[35]

Evaluation of SDM (RO2)

OPTION-5 total and item scores were reported using descriptive statistics. To assess whether the use of POFs was associated with increased SDM behaviour, the differences between OPTION-5 total scores for preobservations and postobservations were analysed through linear mixed-model analyses. A dummy variable indicating preobservations or postobservations was included as fixed effect and a therapist identifier as random effect. As primary analysis, we analysed all preobservations and postobservations that were collected, and as sensitivity analysis, we restricted the dataset to therapists who participated with both a preobservation and postobservation. We aimed to obtain 30 preobservations and 30 postobservations in total.[35]

Ethical considerations

For RO1, all therapists agreed with the terms and conditions of Chronic CareNet, which included complying with data delivery procedures such as the data used for the purpose of this study. We only used data from patients who provided general consent for the use of their clinical data for research and clinical purposes.[35] Therapists and patients who participated in RO2 were separately

informed and asked for written informed consent. Before taking part, informed consent forms had to be signed by both the therapist and the patient.[35]

Patient and public involvement

Patients were not directly involved in the design, conduct, reporting or dissemination plans of the study. However, continuous collaboration and communication on the study's progress and insights took place with the Dutch patient association for people with cardiovascular diseases.

RESULTS

Evaluation of patient outcomes (RO1)

During the control period, data from 3367 patients with intermittent claudication referred for SET were gathered, with baseline data available for either FWD (n=2847), MWD (n=2847) or HRQoL (n=3066). Complete data at both baseline (T0) and follow-up (T1) were available in 721 patients for either FWD (n=600), MWD (n=601) or HRQoL (n=656). During the experimental period, data were gathered from 1571 patients with baseline data available for FWD, MWD or HRQoL. The POFs were used in all these patients. Among the 1571 patients, 317 patients had complete data at both baseline (T0) and follow-up (T1) (FWD: n=315, MWD: n=316, HRQoL: n=317). A flow chart on the inclusion process is presented in online supplemental appendix 2.

Baseline characteristics are shown in table 1 for patients with both baseline and follow-up data. During the experimental period, we observed more never-smokers, fewer former smokers and lower baseline HRQoL scores compared with the control period. These differences were of a small magnitude (ie, substantially smaller than the minimal important difference), and thus were not considered clinically meaningful.[49 50] In online supplemental appendix 2, baseline characteristics for patients categorised by cluster are shown.

In figure 2, the results of the primary analysis (per-protocol principle) are shown. Patients included during the experimental period improved on FWD by an average of 129% (SD=8.9), whereas patients included during the control period improved by an average of 108% (SD=23.6). For MWD, the experimental group improved by an average of 106% (SD=47.7), and the control group improved by an average of 87% (SD=43.1). The differences in improvements between groups on both FWD and MWD did not reach statistical significance (FWD: experimental vs. control=+23%, p=0.11, 95% CI=−5.2% to 50.5%, MWD: experimental vs. control=+21%, p=0.08, 95% CI=−2.4% to 45.2%). For HRQoL, the experimental group improved by an average of 25% (SD=14.7), and the control group improved by an average of 21% (SD=8.1). The difference in improvements between groups on HRQoL did reach statistical significance in favour of the experimental group (experimental vs. control=+4%, p=0.04, 95% CI=0.3% to 8.7%). In online supplemental appendix 2, the median relative changes per time point per cluster are shown.

Table 1 Baseline characteristics of patients with baseline and follow-up data (RO1)

	Control period n=721	Experimental period n=317
Age in years	*n=720*	*n=313*
Mean (SD)	70 (8.93)	70 (8.55)
Sex	*n=721*	*n=317*
Male, n (%)	430 (60)	194 (61)
Female, n (%)	291 (40)	123 (39)
BMI (kg/m2)	*n=612*	*n=316*
Mean (SD)	27 (4.69)	27 (4.14)
Smoking status	*n=678*	*n=317*
Current, n (%)	254 (38)*	112 (35)*
Former, n (%)	375 (55)*	118 (37)*
Never, n (%)	49 (7)*	87 (27)*
FWD in metres	*n=674*	*n=317*
Median (IQR)	260 (157–432)	250 (150–400)
MWD in metres	*n=674*	*n=317*
Median (IQR)	380 (235–620)	360 (214–567)
HRQoL (6–24)	*n=691*	*n=317*
Median (IQR)	16 (13–19)†	15 (12–18)†

*Significant difference (p<0.05) between control and experimental group (χ^2 test).
†Significant difference (p<0.05) between control and experimental group (Mann-Whitney U test).
BMI, body mass index; FWD, functional walking distance; HRQoL, health-related quality of life; MWD, maximal walking distance; RO1, research objective.

In the sensitivity analysis (intention-to-treat principle) (for details, see online supplemental appendix 3), complete data at both baseline and follow-up were available in 957 patients during the experimental period (FWD: n=641, MWD: n=641, HRQoL: n=896). In these data, it was unknown whether the POFs were used or not. The analysis showed no statistically significant differences in improvements between the groups on both FWD and MWD (FWD: experimental vs. control=+6%, p=0.55, 95% CI=−13.2% to 24.5%, MWD: experimental vs. control=+3%, p=0.72, 95% CI=−11.7% to 18.9%). For HRQoL, patients included during the experimental period had a statistically significant greater improvement of 6% (p<0.001, 95% CI=3.2% to 9.7%) compared with patients included during the control period.

Evaluation of the level of SDM (RO2)

A total of 36 preobservations and 20 postobservations were obtained that fulfilled the eligibility criteria (see online supplemental appendix 4 for a flow chart) from a total of 40 therapists. From 16 therapists, we collected both a preobservation and postobservation. Characteristics

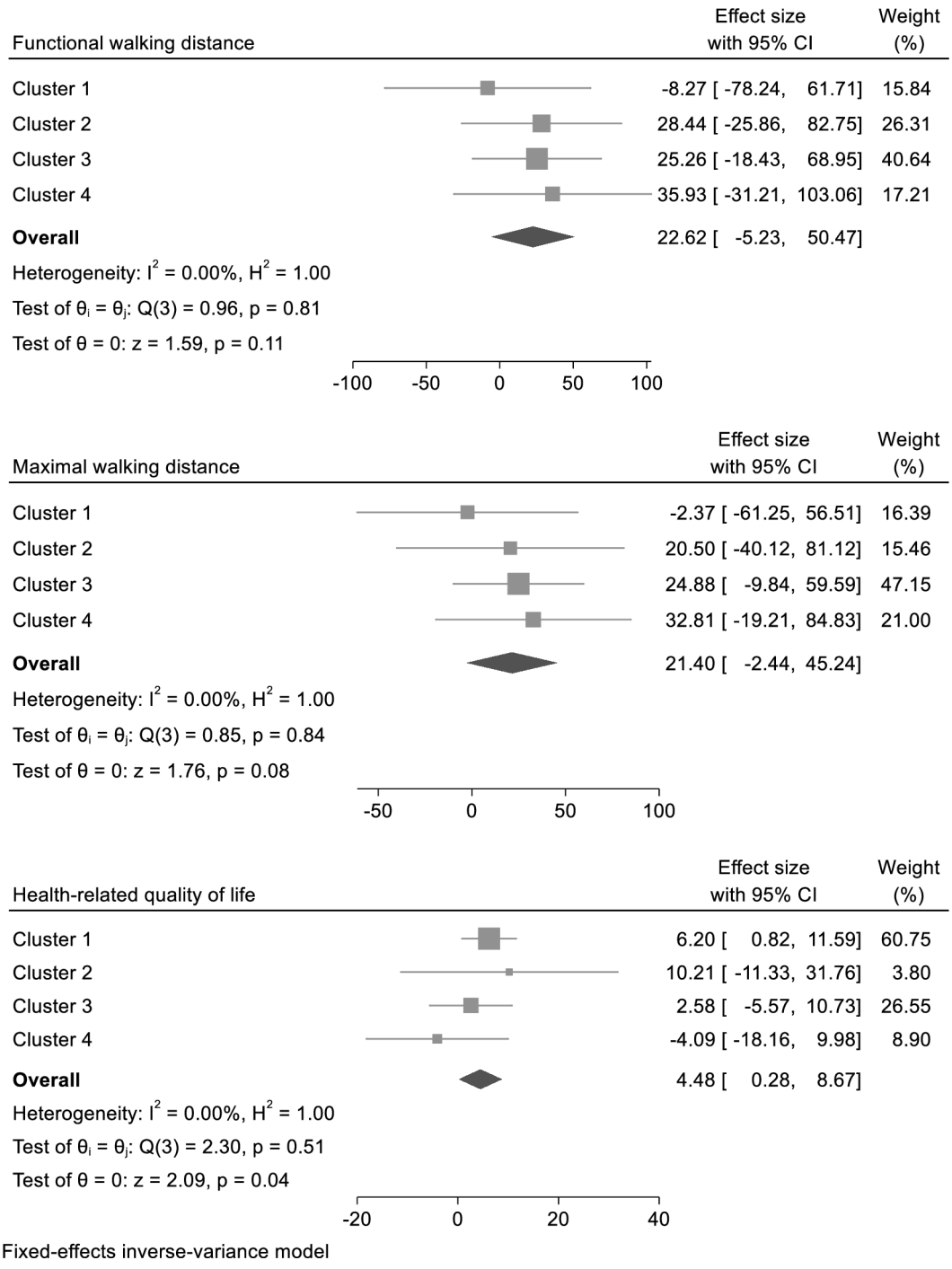

Figure 2 Forest plots of differences before and after the implementation of the POFs on patient outcomes. Results are based on pooled meta-analyses of mean differences per cluster. POFs, personalised outcomes forecasts.

of therapists and patients are shown in table 2. Between preobservations and postobservations, some therapists practised discussing the POFs with only one patient (n=5; 25%), while other therapists practised with more than 10 patients (n=3; 15%). This difference was independent of the time between the preobservation and postobservation. Therapists for whom both an analysable preobservation and postobservation were collected (n=16) had a mean age of 41 years (SD=11.0) and 50% were male. In these paired observations, the duration of postobservations (median=15 min, IQR=9–23) was significantly shorter (p=0.01) than preobservations (median=25 min, IQR=13–47).

Mean and median OPTION-5 total and item scores are shown in table 3. The primary analysis showed that the observed level of SDM in postobservations was significantly higher (median OPTION-5 total score: 55 points) than in preobservations (median: 45 points) (p=0.01, 95% CI 1.6 to 12.7). A visualisation of the OPTION-5 total scores and a detailed overview of the OPTION-5 item scores are presented in online supplemental appendix 4.

Table 2 Demographic characteristics of therapists and patients (in which an analysable observation was collected) and consults (RO2)

	Preobservations (n=36)	Postobservations (n=20)
Physical therapists		
Age in years		
Mean (SD)	42 (11.84)	41 (9.98)
Sex		
Male, n (%)	22 (61)	10 (50)
Female, n (%)	14 (39)	10 (50)
Affiliated with Chronic CareNet in years		
Median (IQR)	7 (3–9)	7 (3–9)
Average no of patients with IC treated per year		
Median (IQR)	9 (6–12)	8 (5–10)
No of patients in which the POFs were practiced		
Median (IQR)	–	3 (1–7)
Patients		
Age in years		
Mean (SD)	72 (9.82)	73 (8.60)
Sex		
Male, n (%)	22 (61)	8 (40)
Female, n (%)	14 (39)	12 (60)
Disease duration in years		
Median (IQR)	1 (0.4–4.8)	1 (0.4–2.0)
Functional walking distance in metres	n=*34*	
Median (IQR)	225 (135–335)	275 (133–378)
Maximal walking distance in metres	*n=35*	
Median (IQR)	360 (230–514)	330 (247–510)
No of comorbidities	*n=34*	
Median (IQR)	1 (1–3)	1 (0–2)
Consults		
Duration in minutes		
Median (IQR)	26 (13–37)	17 (11–25)

IC, intermittent claudication; POFs, personalised outcomes forecasts; RO, research objective.

The sensitivity analysis (ie, the paired preobservations and postobservations) also showed an increase in the median total score of 10 points from 45.0 to 55.0. In terms of effect size, our sensitivity analysis was largely comparable to the results of the primary analysis (p=0.06, 95% CI −0.2 to 14.6).

Table 3 Mean and median OPTION-5 total and item scores

	Preobservations (n=36)		Postobservations (n=20)	
	Mean score (SD)	Median score (IQR)	Mean score (SD)	Median score (IQR)
Item 1: presenting options	2.08 (0.60)	2 (2–2)	2.25 (0.64)	2 (2–3)
Item 2: forming partnership	1.19 (0.53)	1 (1–1)	1.25 (0.44)	1 (1– 2)
Item 3: informing about options	1.42 (0.50)	1 (1–2)	1.50 (0.95)	1 (1–2)
Item 4: eliciting preferences	2.42 (0.73)	2 (2–3)	2.70 (0.92)	3 (2–3)
Item 5: integrating preferences	2.06 (0.92)	2 (1–3)	2.90 (0.72)	3 (3–3)
Total score (out of 100)	45.83 (9.45)	45 (40–50)	53.00 (12.18)	55 (50–55)

DISCUSSION

This study assessed differences in patient outcomes (walking distance and quality of life) and the level of SDM before and after the implementation of POFs in the conservative treatment of patients with intermittent claudication. Statistically significant greater improvements were seen in HRQoL scores in patients with whom POFs were discussed, compared with patients before the implementation. Differences in improvements on FWD and MWD scores did not reach statistical significance. We also found a statistically significant increased level of SDM in conversations at the start of the treatment in which the POFs were discussed, compared with conversations before the implementation. Sensitivity analyses largely align with primary analyses, indicating the robustness of our findings.

We observed a statistically significant increase in the median OPTION-5 total scores of 10 points. Although there is no known MID for the OPTION-5, both items on patients' preferences (item 4 'eliciting preferences' and item 5 'integrating preferences') increased from a 'moderate' effort to a 'skilled' effort. Conversely, item 2 'forming partnership' and item 3 'informing about options' remain at 'minimal' effort, which shows there is still room to improve SDM behaviour. Interestingly, OPTION-5 total scores both before and after the implementation were higher than those reported in previous studies in physical therapy settings[30 51] and those reported in a systematic review of studies using the OPTION-5 instrument.[52] While the studies in physical therapy settings used the OPTION-12, which is known to consistently score lower than the OPTION-5, the actual level of patient involvement is scored the same in both instruments.[53] Our higher scores could be explained by the fact that over the last decade, there has been an increased focus on personalised care.

Our findings suggest that using POFs primarily impacts process measures and subjective patient outcomes, such as SDM and HRQoL, rather than objective patient outcomes, such as FWD or MWD. It seems plausible that patients' perceived quality of life involves more than measured walking distances.[54] Therefore, the observed differences in SDM and HRQoL could potentially be attributed to broader conversations and motivations initiated by using POFs, extending beyond the scope of walking, such as lifestyle modifications. In a vignette study conducted by Sinnige *et al*, therapists suggested that the POFs could provide a springboard for setting secondary therapy goals together, such as gaining strength or increasing daily activity.[26] Exposure to and discussion of the POFs might have supported therapists in making shared decisions and encouraged patients to invest in their overall functioning.

Observed improvements in walking distances did favour patients with whom the POFs were discussed, but those differences were not statistically significant. It is possible the study was underpowered to detect statistically significant differences, as there was a large amount of variability in walking distance values. Although FWD and MWD improved during both the control and experimental period at patient level, our point estimates suggest that improvements were 23% and 21% greater during the experimental period, corresponding to an absolute greater increase of 50 m for FWD and 57 m for MWD. Despite the fact that these improvements were not statistically significant, we deem their positive trend, in combination with the improved outcomes in HRQoL and SDM, as a positive sign, warranting further implementation.

Limitations

First, the use of routinely collected data for RO1 resulted in missing data, which contributed to not meeting the targeted sample size. Many patients were excluded from analysis due to incomplete or missing follow-up measurements within the databases. Reasons for missing data could be attributed to patient factors (eg, early termination of therapy) or to therapist inconsistencies in what and when to document.[55] This lost to follow-up may have introduced bias in the results, particularly since patients lost to follow-up tend to have lower baseline scores (data not shown). Nevertheless, these differences in baseline scores did not exceed the MID thresholds.[49 56] Second, baseline smoking status significantly varied between patients included in the control and experimental period, for which we did not adjust in our analyses. Although this could have resulted in selection bias, it should be mentioned that our aim was to assess and report differences, rather than demonstrating specific effects. Third, we originally aimed to perform a segmented regression analysis for RO1.[35] However, we encountered challenges in comparing the change in level between the control and experimental period due to non-linear and non-consistent changes in trends in both periods. Therefore, we adjusted the analysis to a pooled meta-analysis of mean differences. Although we deviated from the original analysis, we believe a pooled meta-analysis is a robust statistical method that enabled us to draw meaningful insights from the data. Fourth, our findings on the impact of the POFs on the level of SDM might be partially explained by volunteer bias since therapists had the voluntary choice to participate, and by selection bias due to therapists selecting patients to participate with. We aimed to reduce this risk by explicitly explaining to therapists that all patients were eligible to include. Nonetheless, it is possible that therapists attempted to participate with more motivated or socially skilled patients to improve their performance. Finally, there was potential observer bias since the raters of the observations could not be blinded to group assignment (ie, discussion of POFs during clinical consultations would inevitably alert raters to the group assignment). To attempt to minimise the bias associated with this unavoidable limitation, we conducted a robust calibration stage with extensive exposure to the rating protocol and standardised instructions (available on request).

Implications for future practice

Although this is the first study to evaluate the impact of implementing POFs, we believe that integrating POFs into daily practice of SET for patients with intermittent claudication might assist a selection of therapists in providing tailored information, guiding and support to help patients achieve their therapy goals. Although we consider the POFs as a major step forward, we do see opportunities to further improve personalisation of care for patients with intermittent claudication by integrating the POFs with a preference elicitation tool, based on the physical therapy guidelines on intermittent claudication. So, we imagine a decision support system which stimulates therapists to monitor and discuss patient's prognosis, while also stimulating patients to elicit their preferences regarding the treatment plan, thereby fostering an environment that enhances personalised care.

CONCLUSION

This study provides valuable first insights into the potential benefits of a more personalised approach for SET in patients with intermittent claudication by using POFs. Our findings show statistically significant improvements in HRQoL and SDM when comparing preimplementation and postimplementation periods. Use of POFs did not result in statistically significant different improvements between groups on walking distances. Our results suggest that integrating POFs into daily practice of SET for patients with intermittent claudication could potentially assist therapists in enhancing patient involvement and improving quality of life.

Author affiliations
[1]Radboud university medical center, IQ Health science department, Nijmegen, The Netherlands
[2]Chronisch ZorgNet, Eindhoven, The Netherlands
[3]Department of Surgery, Catharina Hospital, Eindhoven, The Netherlands
[4]Physique Preventiecentrum B.V, Arnhem, The Netherlands
[5]Physical Therapy Sciences, Program in Clinical Health Sciences, Utrecht University, Utrecht, The Netherlands
[6]School of Physical Therapy and Rehabilitation Science, University of Montana, Missoula, Montana, USA
[7]Department of Vascular Surgery, Catharina Hospital, Eindhoven, The Netherlands
[8]CAPHRI Research School, Maastricht University Medical Centre+, Maastricht, Netherlands
[9]Clinical Research and Leadership, The George Washington University School of Medicine and Health Sciences, Washington, District of Columbia, USA

Acknowledgements The authors thank L. van den Berg (LB), T. van den Berg (TB), J. Huisman (JH) and M. Hanekamp (MH) for their contribution to the scoring of observations, C. Braam (CB) for her overall help with the project, and all the therapists and patients with intermittent claudication for participation in this study.

Contributors AS, AK, JAWT, PJvdW, SS and TJH contributed to the conceptualisation of the research idea and research design. AS, KMR and LHMM contributed to the data collection, and AK, LHMM and TJH to the data analysis. The main body of the manuscript was written by LHMM, AK, SS and TJH. All authors read, reviewed and approved the final manuscript. AS, SS and TJH managed the project. JAWT, SS and TJH obtained funding. TJH supervised the project and is the guarantor responsible for the overall content.

Funding This study was funded by a grant from the National Health Care Institute (Zorginstituut Nederland).

Competing interests The authors reported no conflicts of interest. JAWT, LHMM and SS are affiliated with Chronic CareNet. AS, AK and TJH developed the POFs.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants but Ethics Committee of Arnhem-Nijmegen, number 2020-6250 exempted this study. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Deidentified participant data are available on reasonable request from TJH (email: Thomas.Hoogeboom@radboudumc.nl).

ORCID iDs
Laura H M Marcellis http://orcid.org/0000-0002-7121-4503
Anneroos Sinnige http://orcid.org/0000-0001-7635-1593
Andrew Kittelson http://orcid.org/0000-0002-0416-8703
Joep A W Teijink http://orcid.org/0000-0001-7927-6904
Philip J van der Wees http://orcid.org/0000-0003-2881-5159
Thomas J Hoogeboom http://orcid.org/0000-0003-2103-419X

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