A digitally supported shared decision-making approach for patients during cardiac rehabilitation: a randomized controlled trial

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Aims

The aim of the study is to evaluate the effectiveness of combining centre-based cardiac rehabilitation (CR) with shared decision-making (SDM) based telerehabilitation (TR) on patients' quality of life, cardiorespiratory fitness, and physical activity level.

Methods and results

A randomized controlled trial (NCT05026957) was conducted with 80 patients with heart disease recruited from Jessa Hospital, Hasselt. Patients were randomized to either a control group receiving standard CR or an intervention group receiving standard CR with additional SDM-based TR via the SharedHeart smartphone application. Primary outcome was quality of life (HeartQoL), while secondary outcomes included cardiorespiratory fitness (VO₂peak) and physical activity levels. Data were analysed using a linear mixed model. The intervention group showed a greater improvement in quality of life [4.15 points, 95% confidence interval (Cl): 0.7-7.6; P=0.02], peak oxygen uptake (VO₂peak) (1.1 mL/kg/min, 95% Cl: 0.04-2.1; P=0.04), and number of step count [14 788 more steps/7 days (95% Cl: 4.2-25.3; P<0.01)] over a 12-week intervention, compared with the control group.

Conclusion

This study demonstrated that the addition of SDM-based TR programme to centre-based CR significantly improved patients' quality of life, cardiorespiratory fitness, and physical activity levels compared with centre-based CR alone. The SharedHeart study stands out as one of the first to integrate a digitally supported SDM approach in CR, empowering patients to take an active role in their rehabilitation. Future research should focus on the long-term impact of digital interventions, particularly in reducing adverse cardiovascular events and enhancing patient self-management.

Lay summary

This study examines how combining traditional centre-based cardiac rehabilitation with a shared decision-making (SDM) approach supported by digital tools impacts the quality of life, fitness, and physical activity levels of patients with heart disease. Key findings

- Adding an SDM-based telerehabilitation programme using the SharedHeart application to standard cardiac rehabilitation significantly improved patients' quality of life (HeartQoL), fitness (VO₂peak), and physical activity (step count) after 12 weeks.
- The integration of a patient-centred SDM approach with digital tools empowers patients to take an active role in their rehabilitation, leading to better adherence and improved outcomes.

This research highlights the potential of integrating SDM and digital applications to enhance cardiovascular rehabilitation programmes.

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Structured Graphical Abstract Key Question

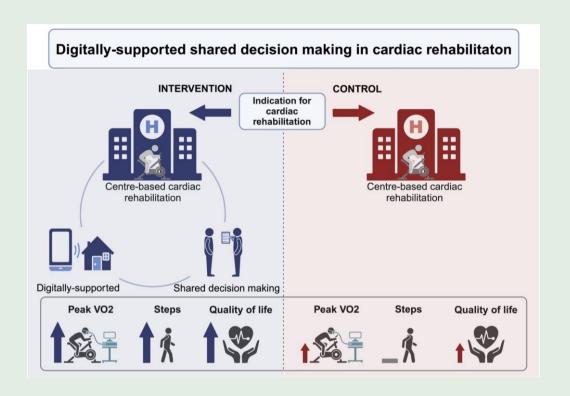
Can a SDM approach supported by digital tools improve quality of life, cardiorespiratory fitness, and physical activity levels in patients undergoing CR?

Key Finding

The SDM-based TR programme significantly improved quality of life, cardiorespiratory fitness, and physical activity levels compared with standard centre-based CR alone.

Take-home message

Incorporating a patient-centred, SDM-based digital programme into CR enhances patient outcomes, emphasizing the importance of personalized, collaborative care in cardiovascular health.



Keywords

Shared decision-making • Cardiac rehabilitation • Cardiac telerehabilitation • Decision aids • Physical activity • eHealth

Introduction

Cardiovascular diseases (CVDs) are the leading causes of morbidity and mortality worldwide. 1,2 In Europe, CVD accounts for more than 1.7 million deaths annually, representing 32.7% of all deaths. 2 According to the 2021 European Society of Cardiology (ESC) guidelines, cardiac rehabilitation (CR) is recommended after an acute cardiovascular event (class IA recommendation). 3 However, participation rates in CR programmes remain suboptimal, as demonstrated by the EUROASPIRE V study. 4

Cardiac telerehabilitation (TR) can play a key role in this care delivery strategy. Telerehabilitation involves the use of digital tools such as mobile applications, wearable devices, and teleconsultations to deliver the core components of CR.^{5–9} Multiple trials have already established that TR is effective, ^{10–21} and a systematic review has recently confirmed the effectiveness of TR in chronic coronary syndrome.⁹

However, most TR programmes do not adequately involve patients in designing their exercise plans, which can limit both the effectiveness

of the intervention and patient adherence. This may also limit the incorporation of these exercises into their daily lives, often leading to a loss of the gained peak oxygen uptake (VO₂peak) after completing CR. Research suggests that involving patients in decision-making improves satisfaction, adherence, and health outcomes.²⁰ Based on the experience of Telerehab III^{5,21} and the Hearthab pilot study and prospective cross-over trial, 22,23 this study wants to investigate whether combining standard centre-based CR with an shared decision-making (SDM)-driven TR programme (via the SharedHeart applications) leads to better outcomes than standard CR alone. Patients and their caregivers set up together a tailored exercise programme in order to get patients involved in making their own decisions about their physical activities and in trying to improve long-term adherence to physical activity. The best available evidence is combined, utilizing the EXPERT tool for personalized exercise prescription 24,25 alongside the patient's personal preferences, values, goals, and context to develop an exercise programme aligned with current European guidelines for physical activity, integrating as many of the patient's personal preferences as possible.

This study aimed to investigate the effectiveness of combining centre-based CR with a SDM approach supported by digital applications to improve quality of life, cardiorespiratory fitness, and physical activity in patients with heart disease. It was hypothesized that integrating SDM with digital support into centre-based CR would lead to greater improvements in these outcomes compared with standard rehabilitation approaches.

Methods

Patient recruitment

SharedHeart (NCT05026957) was a monocentric, prospective randomized controlled clinical trial. All 80 patients were recruited from the Cardiology Department of Jessa Hospital Hasselt in Belgium over a timeframe of 8 months (from November 2022 to June 2023).

Eligible patients included those who entered ambulatory CR at Jessa Hospital Hasselt; were clinically stable, 18 years or older, and able to follow the technology-supported SDM programme; had access to a smartphone with an Android operating system with internet connectivity; and were able to speak and understand Dutch. Exclusion criteria included conditions preventing participation in a technology-supported programme, planned interventions or surgery, cardiovascular complaints, or participation in other similar trials.

Each patient provided evidence of a personally signed and dated informed consent, indicating that they had been informed of all pertinent aspects of the study and agreed to participate.

Patients who were eligible for participation were contacted face-to-face by the study staff before their baseline cardiorespiratory fitness at the start of the CR programme. They were randomly assigned (1:1) to SDM-based TR in addition to usual care CR (intervention group) or usual care CR alone (control group).

Based on means and standard deviations of Brouwers et al. and calculating for continuous variables for two independent study groups with $\alpha=5\%$ and anticipated power of 80% to detect clinically significant differences in the intervention group compared with the control group, the sample size needed to obtain a significant difference in the primary outcome was calculated to be 52. To allow for a 30% dropout rate, a total of 80 patients were included in the trial. A dropout was defined as any participant who discontinued their involvement in the study before the first additional measurement point, after 6 weeks.

Study design

Usual care cardiac rehabilitation

All patients followed a centre-based usual care CR programme (typically 12 weeks) offered at Jessa Hospital Hasselt. This usual care CR programme at the Jessa Hospital Hasselt consists of 45 multidisciplinary rehabilitation sessions with at least two exercise training sessions every week. Every training session had a duration of 60 min, targeting a workload between their first ventilatory threshold (VT1, identified by the V-slope method) and the respiratory compensation point [RCP, identified by the carbon dioxide equivalent (VE/ VCO2) slope method], as in line with the EAPC recommendations.² Both resistance training and endurance training were provided. The endurance training comprised activities such as walking/running, cycling, and arm cranking. Each patient also had at least one session with a dietitian and a psychologist. The dietitian provided general and personalized healthy eating guidelines, while the psychologist worked on improving the patients' confidence in making healthier lifestyle changes and evaluated any mood disorders (e.g. depression, anxiety) related to their cardiac incident. Depending on their needs, more individual counselling sessions could be planned. Each patient also participated in a consultation and cardiopulmonary exercise test with the cardiologist at the beginning, middle, and end of the programme.

Telerehabilitation and shared decision-making

Patients in the intervention group received on top of the usual care CR programme an SDM approach supported by the SharedHeart digital tool and a personalized training prescription developed with the support of the

EXPERT tool. ^{24,25} The EXPERT tool is a decision support system that integrates patient-specific data, including medical history, physical capacity, and personal preferences, to generate a tailored exercise prescription aimed at optimizing rehabilitation outcomes. The SharedHeart digital tool consists of a tablet application, a smartphone application, and a dashboard, designed to support patients in managing their physical activity through SDM with their healthcare providers. It allows patients to track their activities, check their progress with respect to the training goal based on the EXPERT tool's exercise prescription, and receive personalized exercise programmes, all aimed at enhancing adherence to rehabilitation programmes. ²⁸

The patients participated in SDM encounters with their caregivers (cardiologist and physiotherapist) and used the SharedHeart smartphone application at home to manage their physical activity. The frequency of the SDM encounters gradually declined. During the first 6 weeks of the study, patients had an SDM encounter with a physiotherapist every week. In the following 6 weeks, they had such an encounter every 2 weeks (as depicted in Figure 1).

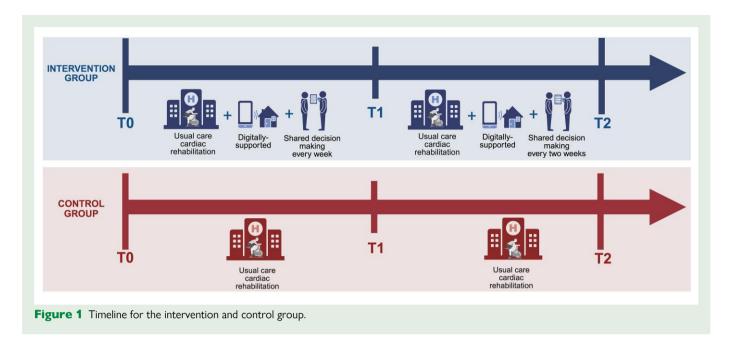
The first consultation with their cardiologist was an SDM encounter, when patients used the SharedHeart tablet application to rank physical activities in their order of preference and entered information about their physical limitations and context. During this SDM encounter, the patient and cardiologist discussed the patient's preferences for physical activity (e.g. cycling vs. walking) and collaboratively define the patient's exercise programme for the upcoming week. The design of SharedHeart dashboard components, targeting both patients and healthcare providers, stimulated discussion and provided guidance in creating the exercise programme. After this first encounter with the cardiologist, these SDM encounters were primarily guided by physiotherapists.

Between the encounters, patients used the SharedHeart smartphone application to report on the physical activity they performed and to monitor their progress with respect to the training goal. The smartphone application allowed patients to report the activities scheduled in their pre-constructed programme that they actually performed. In addition, they could add new activities. Furthermore, patients could consult their history of physical activity, watch videos to improve their knowledge, report on the non-exercise related physical activities they did as part of their daily living (e.g. cleaning, gardening, and mowing the lawn), and take notes about things they wanted to discuss in an upcoming appointment with their physiotherapist. During the week, physiotherapists could use the SharedHeart dashboard to monitor the physical activities their patients performed. In addition, they could prepare for the encounters by consulting the notes that patients took and following up on the patients' long-term progress.

At the next SDM encounter, the patient and physiotherapist discussed the activities of the past period aided by the SharedHeart dashboard. They discussed the patient's adherence to the exercise programme and altered the scheduled programme to encourage the patient to comply with it, while striving for adherence to the guideline-based individual programme generated by the EXPERT tool. During the week(s) after this SDM encounter, the patient tried to complete the adapted programme, and at the next SDM encounter, the process was repeated. As previously mentioned, the frequency of the SDM encounters with discussion of the exercise programme gradually decreased, since week by week the exercise programme became more feasible and better suited to the patient's profile. When the patient finished the supervised rehabilitation in the rehabilitation centre, the intervention was concluded, which meant that the SDM encounters and support from the smartphone application ended.

Outcome measures Baseline characteristics

At baseline, socio-demographical information, a blood sample, clinical information, and current medication therapy were collected for all patients. Furthermore, a fasting blood sample was done after 6 weeks (± 1 week) of CR and is part of standard care in the CR programme at Jessa Hospital Hasselt. The fasting blood sample was used to determine LDL, HDL, triglycerides, total cholesterol, blood glucose, and HbA1c.



Primary outcome

The primary outcome was the difference in quality of life measured with the HeartQoL questionnaire²¹ at the start of the CR programme and the end of the CR programme (12 weeks after randomization). This HeartQoL questionnaire consists of 14 items with a physical (10-item) and emotional (4-item) subscale.

Secondary outcome

The secondary outcomes were as follows:

- Improvement of cardiorespiratory fitness (change in VO₂peak) at the end of the CR programme, determined using a cardiopulmonary exercise testing (CPET)
- Difference in the first and second ventilatory threshold measured at the start and at the end of CR
- The total number of steps, determined with an external wrist-worn accelerometer (Fitbit Charge 5) during the first and the last week of the CR programme (Fitbit Charge 5)

Statistical analysis

A linear mixed model (LMM) was used to account for the repeated measures within patients. The model included fixed effects for the treatment group, time point, and treatment-by-time point interaction, as well as a patient-specific random intercept. To account for the correlation of measurements within patients, a random intercept was included for each patient. The model assumptions were evaluated using residual and QQ plots. In the presence of model violations, a natural logarithm transformation of the outcome was performed to ensure the appropriateness of the model.

The primary hypothesis of the study was the comparison of the change (T2-T0) in quality of life between the treatment groups. No adjustment for multiple testing was performed as this was the sole primary hypothesis. For secondary outcomes (e.g. VO_2 peak, step count), no correction was applied either, as each was pre-specified and analysed in separate models based on clinical relevance. A *P*-value smaller than 0.05 was considered statistically significant, and results for secondary endpoints should be interpreted with caution due to the potential for inflated type I error.

Continuous variables were reported as means with standard deviations (mean \pm SD). The statistical analyses were performed in SAS, version 9.4.

The analysis was conducted on an intention-to-treat (ITT) basis, ensuring that all randomized patients were included in the analysis, regardless of their adherence to the intervention. To handle missing data due to dropouts, a mixed model with maximum likelihood estimation was used, which allows for the inclusion of incomplete cases by using all available data without imputing missing values.

Results

A total of 80 patients consented to participate in the study, with 40 assigned to the control group and 40 to the intervention group (Figure 2).

Baseline demographics and clinical characteristics

Baseline demographics and clinical characteristics are shown in Table 1.

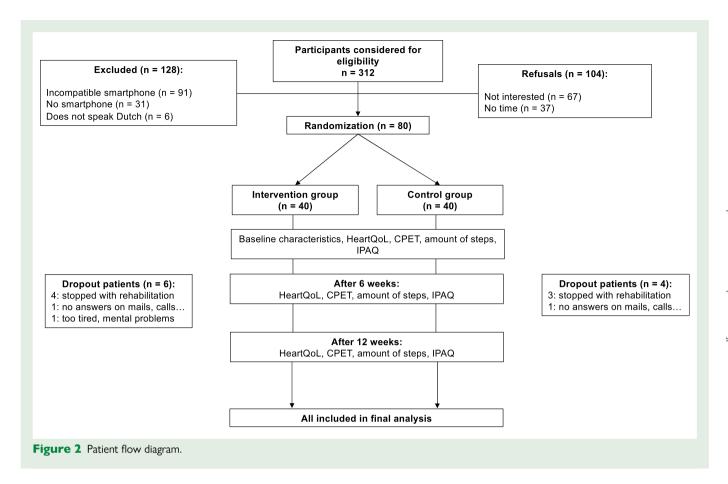
Quality of life (HeartQoL)

Both the intervention (P < 0.01) and control (P < 0.01) groups showed improvements in global quality of life (QoL) during the study period (Figure 3A). However, the intervention group demonstrated a greater improvement compared with the control group, with between-group difference of 4.15 points [95% confidence interval (Cl): 0.7–7.6; P = 0.02]. Details on within-group changes and between-group analysis are presented in Table 2.

While both the intervention and control groups experienced improvements in the emotional subscale (*Figure 3B*), the intervention group achieved greater gains, as reflected by the between-group difference (P = 0.02). Similarly, physical subscale scores improved in both groups, but unlike the emotional subscale, the intervention group's advantage over the control group did not reach statistical significance (P = 0.07). These findings highlight a stronger impact of the intervention on emotional well-being compared with physical aspects.

Cardiorespiratory fitness

 VO_2 peak improved in both the intervention and control groups during the study (P < 0.01 for both; Figure 3D). Notably, the intervention group



showed a superior increase, with a between-group difference of 1.1 mL/ kg/min (95% CI: 0.04–2.1; P=0.04). Similar trends were observed in cycling power output (W). Detailed within- and between-group analyses are available in *Table 2*.

For the intervention group, significant increases were observed for several parameters between the start and the end of the study, except for ventilatory threshold 1 (VT1) (b.p.m.). In contrast, no significant changes were found in the control group, except for cycling power output (pred%), VT1 (W), and VT2 (W). Detailed results for all parameters, including HR max, HR max (pred%), cycling power output (pred%), VT1 (W), VT1 (b.p.m.), VT2 (W), and VT2 (b.p.m.), are presented in *Table* 2. Furthermore, between-group analysis showed no significant differences for these parameters (*Table* 2).

Physical activity (step count)

There was an increase in total daily steps for 7 days in the intervention group from baseline to the end of the study (P < 0.01; Table 2). No significant changes in total daily steps were observed in the control group from baseline to the end of the study (P = 0.1). Between-group analysis confirmed that the intervention group's total daily steps improved more than the control group (on average 14 788, 95% CI: 4246–25 331; P < 0.01) from baseline to the end of the study.

The analysis of the Fitbit Charge 5 data showed an increase in time spent in the low-intensity physical activity (LIPA), moderate-to-vigorous physical activity (MVPA), and vigorous-intensity physical activity (VPA), in the intervention group (P=0.05), while no significant changes were observed in the control group (P=0.8). However, between-group comparisons revealed no significant differences in changes over time (P=0.2).

Descriptive statistics of application data

The bar chart in *Figure 4* displays the intervention group's average number of days per week with reports of structured exercise and/or daily activity during the 12-week period. The *y*-axis represents the average number of days per week that patients reported participating in structured exercise (training activity), completing daily activity reports, or both, with values ranging from 0 to 7. The *x*-axis lists the weeks, numbered from 1 to 12. Each bar corresponds to a specific week and shows the average number of reporting days for that week.

The chart demonstrates a commendable level of patient engagement in structured exercise or daily activity reporting over the 12-week period. Patients consistently reported their activities on 3 to 6 days per week over the 12-week intervention.

Discussion

This study demonstrates that adding patient-specific, SDM-based TR programme to a 12-week centre-based CR leads to significant improvements in quality of life, cardiorespiratory fitness, and physical activity compared with standard rehabilitation.

Our results align with prior research showing the effectiveness of TR in enhancing physical fitness and health-related quality of life for patients with CVD. ^{5,8} Similar to findings from the Telerehab III trial, this study suggests that a comprehensive, patient-specific TR programme—incorporating exercise monitoring, coaching, and self-management tools—is crucial for achieving these improvements. ⁵

The SharedHeart study further advances this field by integrating SDM as a structured, ongoing process throughout a digitally supported

Table 1 Baseline demographics and clinical characteristics

	Intervention	Control
	(n = 40)	(n = 40)
Domographics		
Demographics	62 (54.3–67)	65 (58–73.8)
Age (y), median (IQR)	,	30 (75.0)
Sex (male), n (%)	34 (92.5)	` /
Height (cm), median (IQR)	177.5 (168–184.8)	,
Weight (kg), median (IQR)	82 (74–95)	83.5 (71–96.3)
BMI (kg/m ²), median (IQR)	26.1 (23.7–31.5)	
Systolic blood pressure (mmHg), median (IQR)	127.0 (±18.2)	125.0 (±18.0)
Diastolic blood pressure (mmHg),	75.6 (±10.6)	74.8 (±10.5)
median (IQR)		
Indication for cardiac rehabilitation		
Coronary artery bypass grafting, n (%)	2 (5.0)	5 (12.5)
Percutaneous coronary	16 (40.0)	20 (50.0)
intervention, n (%)		
Ablation, n (%)	12 (30.0)	7 (17.5)
PM, ICD, CRT-D, CRT-P, n (%)	5 (12.5)	4 (10.0)
Heart failure, n (%)	3 (7.5)	1 (2.5)
Heart valve repair or replacement,	2 (5.0)	3 (7.5)
n (%)		
Professional profile	4 (40.0)	4 (2.5)
Unemployed, n (%)	4 (10.0)	1 (2.5)
Employed, n (%)	19 (47.5)	19 (47.5)
Retired, n (%)	17 (42.5)	20 (50.0)
Cardiovascular risk factors		
Diabetes mellitus (yes), n (%)	4 (10.0)	8 (20.0)
Hypertension (yes), n (%)	23 (57.5)	25 (62.5)
Dyslipidaemia (yes), n (%)	26 (65.0)	31 (77.5)
Obesity (yes), n (%)	13 (32.5)	10 (25.0)
Smoking (yes), n (%)	3 (7.5)	6 (15.0)
Family history of CVD (yes), n (%) Lab values	19 (47.5)	23 (57.5)
Total cholesterol (mg/dL), median	140 (124–169)	169 (132–196)
(IQR)		
LDL-cholesterol (mg/dL), median (IQR)	74 (56–93)	100 (66–114)
HDL-cholesterol (mg/dL), median	42 (38–56)	41.5 (35–52)
(IQR) Trightcorides (mg/dl.) modian (IQR)	120 (81 152)	174 (70 104)
Triglycerides (mg/dL), median (IQR) HbA1C (%), median (IQR)	120 (81–152) 5.6 (5.4–5.9)	126 (79–184) 5.8 (5.5–6.1)
CPET	` '	` '
VO ₂ peak (mL/min/kg), median	19.2 (14.4–23.8)	18.2 (15.6–22.4)
(IQR) Peak power (W), median (IQR)	151 (110,3–195)	128 (98–171.8)
Cardiac rehabilitation Amount of sessions, median (IQR)	32 (20–44)	36 (25–44)
	()	()

BMI, body mass index; PM, pacemaker; ICD, implantable cardioverter defibrillator; CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; CVD, cardiovascular disease; LDL, low-density lipoprotein; HDL, high-density lipoprotein; HbA1C, haemoglobin A1C; CPET, cardiopulmonary exercise testing; VO $_2$ peak, peak oxygen uptake.

TR programme. Unlike most TR interventions, which offer limited opportunities for patient input, SharedHeart enabled patients to actively co-create their exercise programme in collaboration with healthcare providers over a 12-week period. This approach reflects a shift from static or single-time point decision aids to a dynamic and personalized care pathway. By aligning patients' preferences, values, and contexts with guideline-based prescriptions via the EXPERT tool, the intervention likely contributed to the sustained improvements observed in quality of life, physical activity, and cardiorespiratory fitness.

This study is, to our knowledge, the first RCT to implement a longitudinal, app-facilitated SDM strategy within cardiac TR. While one earlier pilot study by Jiang et al. investigated a hybrid SDM-TR model in patients with COPD,³ no comparable SDM-based TR intervention has yet been tested in cardiac care. Our findings thus provide novel evidence for the feasibility and added value of embedding digital SDM tools in CR.

Furthermore, our results align with a recent meta-analysis showing that SDM in cardiac care improves adherence, decision satisfaction, and ultimately clinical outcomes. An expert consensus also highlighted the benefits of SDM for improving exercise adherence and quality of life in cardiovascular care, In line with the 2021 ESC guidelines, which strongly advocate for patient engagement through SDM.

The primary outcome of the SharedHeart study was the significant improvement in <code>HeartQol</code> scores for the intervention group, underscoring the impact of tailored, patient-centred care on quality of life. By involving patients in the decision-making process, the SharedHeart programme may have contributed to patients' continued engagement with the exercise regimen and fostered a stronger sense of autonomy. This patient engagement, facilitated by the SDM approach, appears to have contributed to the observed quality of life improvements in the intervention group compared with the control group.

An interesting observation in our study is that the intervention led to greater improvements in the emotional than in the physical subscale of the HeartQoL. This may reflect the specific impact of SDM on psychological well-being. By actively involving patients in setting personalized goals, the programme likely enhanced their sense of control and reduced uncertainty—factors that contribute more strongly to emotional than physical outcomes. In contrast, improvements in physical QoL are more directly tied to training intensity and physiological adaptation, which occurred in both groups. These findings align with previous research suggesting that patient-centred approaches particularly benefit psychosocial domains such as stress, satisfaction, and perceived support.

In addition to improved quality of life, the SharedHeart study showed a meaningful improvement in VO_2 peak for the intervention group, with an average difference of 1.1 mL/kg/min, an important indicator of cardiorespiratory fitness. This increase in VO_2 peak has notable clinical relevance for cardiovascular health. In coronary artery disease patients, a comparable improvement is associated with approximately a 25% reduction in hospitalization risk and a 20% reduction in mortality over 2.3 years. For chronic heart failure patients, a 6% improvement in VO_2 peak corresponds to a 8% reduction in the risk of cardiovascular death or hospitalization. These findings suggest that the VO_2 peak gains in the intervention group likely translate into meaningful prognostic benefits across various cardiovascular conditions.

The most substantial gains in VO_2 peak for the intervention group occurred in the second half of the programme, whereas the control group exhibited an upward trend in the first half, which then plateaued during the second half. This pattern suggests that while centre-based CR may lead to initial VO_2 peak improvements,

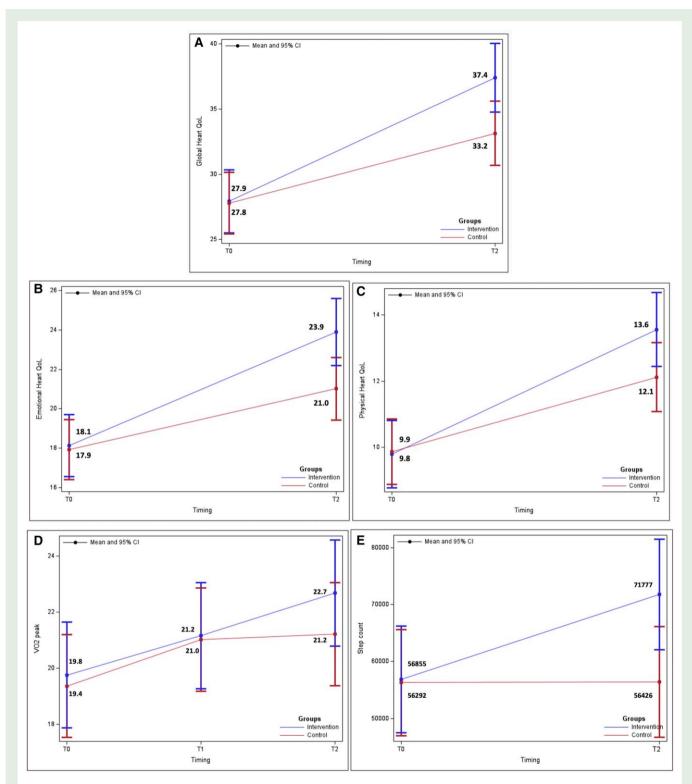


Figure 3 Line charts depicting (A) global HeartQoL, (B) emotional part of the HeartQoL, (C) physical part of the HeartQoL, (D) mean VO_2 peak (mL/[min*kg]), and (E) total daily steps for 7 days, measured by the external wrist-worn accelerometer (Fitbit Charge 5); T0 (week 1) and T2 (week 12); intervention group is represented by the upper line (blue) and control group by the lower line (red).

continued progress in the second 6 weeks likely required additional training beyond standard care. The observed gains during the TR phase indicate that structured, prolonged exercise support can be beneficial. Although our intervention included SDM, we cannot

determine whether this specific format was necessary to achieve the added effect. By enabling patients to manage and personalize their exercise routines, the intervention helped them surpass the plateau typically observed after the initial CR period.

Table 2Results from HeartQoL, cardiopulmonary exercise testing, and physical fitness at baseline, Week 6, and Week12

	Intervention group					Control group			Between-group ∆ 12-1		
	Baseline	Week 6	Week 12	P Δ12-1	Baseline	Week 6	Week 12	P Δ12-1	Estimate	95% CI	P
HeartQoL global score	28	N/A	37	<0.01	28	N/A	33	<0.01	4	0.7–7.6	0.02
VO ₂ peak (mL/[min*kg])	19.8	21.2	22.3	< 0.01	19.4	21.0	21.2	< 0.01	1.1	0.04-2.1	0.04
HR max	129	131	137	< 0.01	123	124	126	0.3	5	-2-12	0.2
HR max (pred%)	80	81	86	< 0.01	80	80	82	0.3	4	-0.7-8	0.09
Cycling power output (W)	153	173	183	< 0.01	140	152	158	< 0.01	12	4–20	<0.01
Cycling power output (pred%)	97	107	116	< 0.01	102	112	116	< 0.01	5	-0.1-11	0.1
VT1 (W)	95	101	115	< 0.01	83	93	97	< 0.01	5	-67-17	0.4
VT1 (b.p.m.)	103	100	106	0.3	99	99	101	0.3	0.6	-6-8	0.9
VT2 (W)	137	156	168	< 0.01	123	134	145	< 0.01	9.5	-0.3-19.3	0.06
VT2 (b.p.m.)	121	127	129	< 0.01	115	118	119	0.09	3	-4 -11	0.4
Step count (Fitbit Charge 5 ®)	56 855	N/A	71 777	<0.01	56 292	N/A	56 426	0.97	14 788	4246-25 331	<0.01
LIPA + MVPA + VPA	387	N/A	516	0.05	392	N/A	335	0.8	119	-67-305	0.2

LIPA, low-intensity physical activity; MVPA, moderate-to-vigorous physical activity; VPA, vigorous-intensity physical activity.

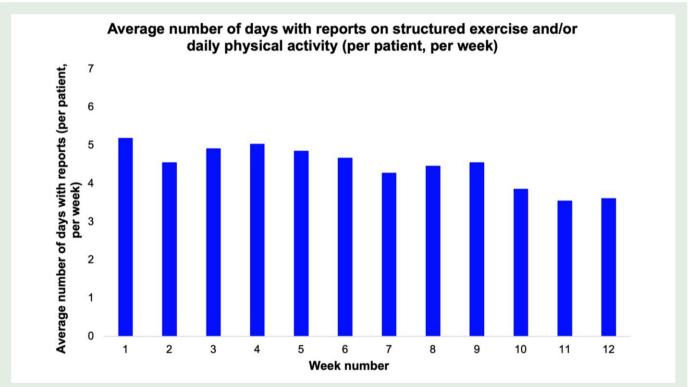


Figure 4 Average number of days per week that the intervention group patients reported structured exercise or daily activity (total duration = 12 weeks).

This pattern aligns with existing research indicating that patients often achieve better performance and adherence in the early stages of rehabilitation, likely driven by initial motivation and the novelty of structured activity. After this initial phase, patients may require additional support or variety to maintain progress. For instance, incorporating higher-intensity modalities, such as high-intensity interval training instead of moderate-intensity continuous training, or increasing resistance

training volume or intensity, may help counteract 'non-responsiveness' in the later stages and sustain gains.³⁵

Dropout rates in this study were relatively low compared with standard CR programmes, with six participants discontinuing in the intervention group and four in the control group. Most dropouts were due to participants discontinuing rehabilitation entirely (five in the intervention group and three in the control group), while a few

resulted from no longer interested in participating in the study (one participant in each group).

The SharedHeart study represents one of the first investigations into the effects of a digitally supported SDM approach during CR. While the findings are promising, several limitations must be considered. First, the study was conducted at a single centre in Belgium with only Dutch-speaking participants, which may limit the generalizability of the findings. A larger, multicentre trial in more diverse and multilingual populations is required to confirm that these benefits extend to other settings, including lower socio-economic status, limited digital health literacy, or limited access to technology. We acknowledge that participants in this trial were likely relatively comfortable with digital tools. Future efforts should ensure that digitally supported programmes are accessible to individuals with limited technological experience or lower digital health literacy. Educational approaches that aim to improve users' confidence and ability to engage with digital tools may help promote digital equity in CR. Second, the follow-up was limited to 12 weeks. We did not assess outcomes beyond the rehabilitation period, so the long-term sustainability of the observed improvements remains unknown. Future research should include extended follow-up (e.g. 6-12 months) to determine whether gains in quality of life, physical activity, and fitness translate into reduced cardiovascular events or hospital readmissions over time. Third, we did not evaluate the costeffectiveness of combining SDM-based TR with CR. Economic analyses in future studies will be important to determine the feasibility of wider implementation of this approach. Fourth, there is a limitation of the investigation of the individual impact of the components within the intervention (digital tools and SDM approach), due to the intrinsic design of the study. Future research could address this by isolating the SDM component, evaluating its effectiveness independently, and comparing it with combined or solely digital interventions. Finally, we did not include any SDM-specific patient-reported outcomes (e.g. decision satisfaction, decisional conflict, or perceived involvement in care), which limits our ability to directly assess the impact of the SDM process itself. Future studies should incorporate such measures to better understand the mechanisms by which SDM contributes to clinical and psychosocial outcomes.

Successful implementation of an SDM-based TR programme in routine practice will require careful consideration of resource and logistical challenges. Regular SDM sessions mean clinicians must allocate time for one-on-one discussions, and robust technical support is needed to deploy and maintain the app, and assist patients. Addressing these practical issues—for example, by training additional staff or simplifying the digital tools—will be crucial for scaling up this approach in real-world settings. ^{20,30}

In addition, ensuring digital equity is essential. Patients with lower digital health literacy (i.e. the ability to access, understand, and use digital tools to manage their health) may face challenges in engaging with app-based interventions.³⁶ This may particularly affect older adults or those with limited access to technology. There is growing evidence that educational interventions can improve digital health literacy in people with chronic diseases.³⁷ Future implementations should therefore consider strategies to identify and support individuals with lower digital skills and explore alternative formats to promote equitable access.

In conclusion, the results of this study support the implementation of a SDM approach, supported by digital tools, in CR. While this study focused solely on SDM for physical activity, future research should explore the effects of a digitally supported SDM approach across all components of CR. Additionally, future studies should focus on optimizing feedback strategies and personalized coaching to maximize

patient engagement and long-term adherence. It is also crucial to evaluate whether such TR programmes can help reduce the risk of cardiovascular events and hospital readmissions over the long term.

Author contribution

S.E.K.: patient recruitment, planning, data collection, analysis, manuscript writing, and editing. Z.P.: statistical analysis. M.S. and C.B.: conceptualization and experiment conduction. M.F., W.R., and M.M.: writing—review and editing. K.C., D.H., M.D.P., and P.D.: conceptualization, writing—review and editing, resources, and supervision. All authors have read and approved the final version of the manuscript.

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Ethical approval

This study was conducted in accordance with the ethical standards outlined in the Declaration of Helsinki. The research protocol was approved by the Ethics Committee of Hasselt University and Jessa Hospital. Informed consent was obtained from all participants prior to their inclusion in the study.

Conflict of interest: none declared.

Data availability

The datasets and materials utilized in this study will be made available to interested researchers upon reasonable request. Access to the data is subject to approval by the corresponding author and is intended to support transparency and the reproducibility of the research. Requests can be submitted to sevda.ece@hotmail.com.

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