



Lifestyle Walking Intervention for Patients With Heart Failure With Reduced Ejection Fraction: The WATCHFUL Trial

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BACKGROUND: Physical activity is pivotal in managing heart failure with reduced ejection fraction, and walking integrated into daily life is an especially suitable form of physical activity. This study aimed to determine whether a 6-month lifestyle walking intervention combining self-monitoring and regular telephone counseling improves functional capacity assessed by the 6-minute walk test (6MWT) in patients with stable heart failure with reduced ejection fraction compared with usual care.

METHODS: The WATCHFUL trial (Pedometer-Based Walking Intervention in Patients With Chronic Heart Failure With Reduced Ejection Fraction) was a 6-month multicenter, parallel-group randomized controlled trial recruiting patients with heart failure with reduced ejection fraction from 6 cardiovascular centers in the Czech Republic. Eligible participants were ≥ 18 years of age, had left ventricular ejection fraction $< 40\%$, and had New York Heart Association class II or III symptoms on guidelines-recommended medication. Individuals exceeding 450 meters on the baseline 6MWT were excluded. Patients in the intervention group were equipped with a Garmin vívoFit activity tracker and received monthly telephone counseling from research nurses who encouraged them to use behavior change techniques such as self-monitoring, goal-setting, and action planning to increase their daily step count. The patients in the control group continued usual care. The primary outcome was the between-group difference in the distance walked during the 6MWT at 6 months. Secondary outcomes included daily step count and minutes of moderate to vigorous physical activity as measured by the hip-worn Actigraph wGT3X-BT accelerometer, NT-proBNP (N-terminal pro-B-type natriuretic peptide) and high-sensitivity C-reactive protein biomarkers, ejection fraction, anthropometric measures, depression score, self-efficacy, quality of life, and survival risk score. The primary analysis was conducted by intention to treat.

RESULTS: Of 218 screened patients, 202 were randomized (mean age, 65 years; 22.8% female; 90.6% New York Heart Association class II; median left ventricular ejection fraction, 32.5%; median 6MWT, 385 meters; average 5071 steps/day; average 10.9 minutes of moderate to vigorous physical activity per day). At 6 months, no between-group differences were detected in the 6MWT (mean 7.4 meters [95% CI, -8.0 to 22.7]; $P=0.345$, $n=186$). The intervention group increased their average daily step count by 1420 (95% CI, 749 to 2091) and daily minutes of moderate to vigorous physical activity by 8.2 (95% CI, 3.0 to 13.3) over the control group. No between-group differences were detected for any other secondary outcomes.

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CONCLUSIONS: Whereas the lifestyle intervention in patients with heart failure with reduced ejection fraction improved daily steps by about 25%, it failed to demonstrate a corresponding improvement in functional capacity. Further research is needed to understand the lack of association between increased physical activity and functional outcomes.

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Key Words: behavior ■ cardiac rehabilitation ■ counseling ■ exercise ■ fitness trackers ■ walk test ■ walking

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Clinical Perspective

What Is New?

- A simple lifestyle walking intervention, combining self-monitoring with an activity tracker and telephone counseling, can increase daily step count in patients with heart failure with reduced ejection fraction by ≈25%.
- The intensity of lifestyle walking interventions may not be sufficient to elicit improvements in their functional capacity.

What Are the Clinical Implications?

- Traditional supervised, structured exercise-based cardiac rehabilitation programs continue to be the standard strategy for improving functional capacity, quality of life, and prognosis in patients with heart failure with reduced ejection fraction.
- These programs can be supplemented with simple lifestyle physical activity interventions, using tools such as activity trackers, to support long-term behavioral change and enhance health outcomes.

Nonstandard Abbreviations and Acronyms

6MWT	6-minute walk test
HF	heart failure
HFrEF	heart failure with reduced ejection fraction
MVPA	moderate to vigorous physical activity
NT-proBNP	N-terminal pro-B-type natriuretic peptide
NYHA	New York Heart Association
PA	physical activity
WATCHFUL	Pedometer-Based Walking Intervention in Patients With Chronic Heart Failure With Reduced Ejection Fraction

Heat failure with reduced ejection fraction (HFrEF) is a substantial burden on global health, contributing significantly to hospital admissions, health care costs, and mortality rates.¹ Physical activity (PA) and exercise are fundamental in managing HFrEF, with potential benefits in improving functional capacity and quality of life and enhancing prognosis.^{2–5} However, the optimal strategy to increase PA in this population remains elusive.⁶

Traditional supervised, structured exercise-based cardiac rehabilitation programs have demonstrated benefits,^{7,8} but their availability and accessibility are often limited, reaching only a fraction of eligible patients.^{9,10} In addition, the demanding intensity of the exercises, logistical issues such as transportation difficulties and inconvenient scheduling, and individual time constraints contribute to lower adherence rates.^{11,12} In addition, these programs often fail to induce sustained behavioral change, resulting in their effect being frequently short-term.¹³

Lifestyle PA interventions have emerged as an alternative approach.¹⁴ These interventions aim to integrate increased PA levels into daily life, often promoting walking as a natural, accessible form of exercise.¹⁵ By focusing on incorporating walking into everyday routines, lifestyle walking interventions offer a more flexible and sustainable solution, potentially addressing the limitations associated with more structured programs.¹⁶ These interventions typically include various behavior change techniques such as goal-setting, action-planning, and self-monitoring.¹³ They commonly use activity trackers to facilitate self-monitoring and often combine this technology with human support (ie, telephone counseling) to enhance adherence and effectiveness.^{17,18} Previous research involving patients with conditions such as chronic respiratory diseases, cardiovascular diseases, or type 2 diabetes has shown that similar interventions can result in substantial step count increases ranging from 1000 to 2000 steps daily.^{17,19–23} Moreover, these step count increments have been linked to significant health benefits, including reduced systolic blood pressure, decreased waist circumference, and lowered low-density lipoprotein cholesterol levels, as well as enhanced functional capacity.^{16,23–25}

Whether lifestyle walking interventions can result in a substantial step count increase among patients with HFrEF and whether such increases transform into enhanced functional capacity remains unexplored.²⁶ The WATCHFUL trial (Pedometer-Based Walking Intervention in Patients With Chronic Heart Failure With Reduced Ejection Fraction) aimed to address this gap by investigating whether a 6-month lifestyle walking intervention, compared with usual care, can elicit improvements in 6-minute walk test (6MWT) distance, a measure of functional capacity, in patients with stable HFrEF.

METHODS

Trial Design

The WATCHFUL trial was a 6-month, multicenter, parallel-group, randomized controlled trial performed from August 2018 to June 2023 at 6 clinical centers in the Czech Republic, of which 4 were tertiary cardiovascular centers, 1 a regional cardiovascular center, and 1 a large outpatient ambulatory center, all providing specialized outpatient heart failure (HF) services (Appendix 1 in the Supplemental Material). The trial protocol received approval from the multicenter Ethics Committee of the General University Hospital in Prague (20/16 grant VES 2017 AZV VFN) and was registered at ClinicalTrials.gov (URL: <https://www.clinicaltrials.gov>; Unique identifier: NCT03041610). The trial protocol and statistical analysis plan have been published in detail elsewhere.^{27,28} Details regarding the deviations from the published protocol can be found in Appendix 2 in the Supplemental Material. The data that support the findings of this study are available from the corresponding author upon reasonable request (Appendix 3 in the Supplemental Material).

Participants

The trial recruited patients ≥ 18 years of age with stable HFrEF (left ventricular ejection fraction $< 40\%$) and New York Heart Association (NYHA) class II or III symptoms on evidence-based medication with maximally tolerated dosages. We excluded patients who had signs or symptoms of decompensated HF, uncontrolled arrhythmia or effort-induced angina, severe or symptomatic aortic stenosis, persistent hypotension, or recent events (< 3 months) such as myocardial infarction, percutaneous coronary intervention, implantation of an implantable cardioverter defibrillator or biventricular pacemaker, or shocks delivered by automated implantable cardioverter defibrillator. Potential participants were screened using the 6MWT and those exceeding 450 meters or unable to complete the test were excluded. For the full set of inclusion and exclusion criteria, see Appendix 4 in the Supplemental Material.

Sample Size

To detect a clinically meaningful change of 45 meters on the 6MWT²⁹ with 80% power using a 2-sided 0.05 significance level (α) and assuming a standard deviation of within-group change of 100 meters, 79 participants were required in each group. Anticipating an attrition rate of 20%, our recruitment

goal was set at 100 patients per group, leading to a total of 200 patients. The clinically meaningful change of 45 meters was derived from the work of Shoemaker et al,²⁹ who triangulated the minimum clinically meaningful difference using various methods of analyzing existing data. The SD for within-group change, set at 100 meters, was on the basis of findings from previous studies.^{29–31}

Randomization and Blinding

Patients were randomized in a 1:1 ratio to either the intervention or control group. Centralized randomization was executed using a computer-automated system to ensure proper allocation concealment. The trial used a permuted block randomization scheme, stratified by center, NYHA class, sex, and age (18–65, ≥ 66), to guarantee balanced group representation.

Given the trial's design, blinding of patients and researchers was not feasible, as both were aware of the allocation because of their active involvement in the intervention. Nonetheless, all assessments were conducted by assessors who remained blinded to treatment allocation.

Intervention and Control Groups

During the clinical visits at baseline, 3 months, and 6 months, all patients were educated about the health benefits of regular PA and encouraged to integrate walking into their daily routine.

Patients in the intervention group participated in a 6-month behavioral lifestyle intervention aimed at seamlessly integrating additional PA, primarily walking, into their daily routines. This intervention used behavior change techniques, including self-monitoring, goal-setting, and action planning, facilitated by 1 of 2 research nurses through regular telephone consultations.

At the baseline visit, patients were equipped with a wrist-worn Garmin vívofit activity tracker to self-monitor their daily step count. The vívofit was chosen because of its simplicity, functioning primarily as a pedometer, making it suitable for our study population of older patients with HF, many of whom had limited experience with advanced smart devices. To maintain this simplicity, we configured the device to avoid any prompts or feedback. However, we did not prohibit participants from altering the Garmin settings or using the Garmin app, allowing them the discretion to personalize their device experience. This approach mirrors how older individuals might use such devices in real-world settings outside of a controlled study environment. The vívofit's extended battery life of at least 8 months alleviated the burden of frequent charging. The vívofit's step-counting accuracy has been previously validated in both laboratory-based and free-living environments. Among the devices tested, it emerged as the top-performing tracker for patients with HF.³² Nevertheless, the inherent simplicity of the device meant it lacked features such as a heart rate monitor or wear sensor, which posed challenges in verifying consistent wear.

The participants were advised to wear the device from waking to sleeping. Participants were instructed not to intentionally increase their activity levels during the initial week to ensure an accurate capture of their habitual daily step count. Furthermore, to bolster patients' adherence to self-monitoring, they were instructed to record their daily steps as indicated by the device in a paper diary and to review this diary at least once a week.

Approximately 2 weeks after the baseline visit, patients in the intervention group were contacted by telephone by 1 of the

2 nurse counselors. The nurse reviewed the patients' average daily step count as recorded by the tracker during the initial week. The patients were then guided to aim for an incremental increase of at least 3000 steps above their baseline gradually over 6 weeks. Targeting an additional 3000 steps daily is a common goal in behavioral interventions.³³ This increment equates to ≈30 minutes of walking, assuming a pace of 100 steps per minute, a heuristic estimate for a moderate-intensity threshold.³³ As a result, this represents >150 minutes of moderate-intensity PA each week, in line with the World Health Organization guidelines for adults with chronic conditions.³⁴ Regular engagement at this activity level has consistently been associated with notable health advantages.³⁴ If patients found the 3000-step increase challenging, they were encouraged to propose a more achievable goal. Studies have shown that goal ownership (ie, a deep personal commitment to a set target) often has a stronger influence on behavior change than the exact numeric value of the goal.³⁵ Therefore, the counselor ensured that patients felt a sense of ownership over their goals rather than feeling that goals were externally imposed. In addition, patients were prompted to identify opportunities to incorporate these additional steps into their daily routines and to formulate their own action plans. Should they encounter challenges in creating these plans, the counselor offered suggestions, such as incorporating walking into daily commutes, postmeal or evening strolls, walking with grandchildren, dog walking, or walking meetings.

In follow-up telephone counseling sessions at 1, 2, 4, and 5 months, the counselor assisted patients in revisiting their step goals and action plans. These sessions focused on addressing any barriers faced, emphasizing the importance of social support, and offering tailored feedback on progress. The counselor also discussed patients' personal goals, monitored adherence, reviewed step diaries, and provided guidance on overcoming challenges to PA. On the basis of the patient's progress, the counselor had the flexibility to adjust the step goals. For example, if a patient regularly surpassed their goal, a higher target might be set. On the other hand, if a patient found the goal unachievable, it could be adjusted downward to maintain motivation and avoid discouragement.

Patients in the control group received usual care, which included education about the health benefits of PA and encouragement to augment their walking routine during clinical visits. However, they did not receive the activity tracker, specific step goals, or regular telephone consultations from the research nurse.

Outcomes

The primary outcome was the difference between groups in the distance in meters walked during the 6MWT at 6 months.

Secondary outcomes at 6 months encompassed PA measures (average daily step count and minutes of moderate to vigorous PA [MVPA]); biomarkers (NT-proBNP [N-terminal pro-B-type natriuretic peptide] and high-sensitivity C-reactive protein); left ventricular ejection fraction; patient-reported outcomes (Beck Depression Inventory II, 36-item Short-Form Health Survey, and General Self-Efficacy Scale); anthropometric measures (body mass index and waist and hip circumference); and Meta-Analysis Global Group in Chronic Heart Failure risk score. 6MWT, NT-proBNP, and body weight were additionally evaluated at 3 months.

For both the intervention and control groups, PA was objectively measured using the Actigraph wGT3X-BT accelerometer. Participants were instructed to wear the device on their right hip during waking hours for a consecutive 7-day period at baseline and 6 months, ensuring consistent measurement across both groups.³⁶ This device recorded raw accelerometry data, which were then aggregated into 60-second epochs. Nonwear time was identified using the Choi algorithm,³⁷ and a valid day was defined as having a minimum of 600 minutes of wear time. Only measurements with at least 4 valid days, including at least 1 weekend day, were considered for analysis.³⁸ The average daily step count was determined using the manufacturer's proprietary algorithm as implemented in the ActiLife software, and minutes of MVPA were calculated on the basis of Freedson cut points.³⁹ Whereas the intervention group also wore the activity tracker, the reported values of step count and minutes of MVPA for both groups were obtained solely through the Actigraph accelerometer.

Adherence to the intervention was gauged on the basis of the percentage of individuals who declined to wear the wrist-worn activity tracker, missed the clinic visit at 3 and 6 months, or participated in fewer than 3 out of the 5 planned telephone counseling sessions. In addition, during each telephone contact, we assessed adherence to self-monitoring with the activity tracker by asking participants whether they maintained their paper diary and inquiring about their recent step count.

Adverse events were consistently monitored and documented throughout the trial duration. Data concerning hospitalizations, HF decompensation, cardiovascular events, falls and injuries, musculoskeletal issues, and fatalities were gathered at each time point.

Detailed descriptions of all outcomes, including exploratory, can be found in the published protocol and statistical analysis plan.^{27,28}

Statistical Methods

The primary analyses were conducted by the strict intention-to-treat principle using a linear mixed-effect model, accounting for clustering at the center level as a random effect and adjusting for baseline value of the respective variables, age, sex, and NYHA class as fixed effects. In addition, supplementary analyses were conducted on the per-protocol population using the same approach; the definition of the per-protocol population is detailed in the published statistical analysis plan.²⁸ Furthermore, for the primary outcome, a supplementary analysis was undertaken in which missing data were imputed using multiple imputations by chained equations with the predictive mean matching method.

Prespecified subgroup analysis was conducted to assess the differential effect of the intervention on patients participating before versus after the onset of the COVID-19 pandemic (March 11, 2020). Additional post hoc subgroup analyses investigated patient subgroups according to baseline 6MWT, daily step count, age, sex, NYHA class, body mass index, NT-proBNP, and Meta-Analysis Global Group in Chronic Heart Failure risk score. Whether intervention effects were significantly different between the complementary subgroups was assessed by conducting interaction tests, with interaction terms incorporated into the linear mixed-effect models, adjusted for covariates as in the primary analysis.

The intervention effect for the primary outcome is presented as the mean, accompanied by a 2-sided 95% CI and the associated *P* value (determined at a 2-sided 5% significance level). For secondary outcomes, only the mean and 95% CI are reported, as adjustments for multiple testing were not made. For the within-group changes, both means (95% CI) and medians (interquartile range) are reported, given that the variables did not exhibit a normal distribution. The normality of the variables was assessed using the Shapiro-Wilk test.

All analyses were conducted using R statistical software (version 4.1.2) and the packages nlme (3.1-153) and mice (3.15.0).

RESULTS

Study Participants

Out of the 218 patients screened, 11 were excluded and 5 declined to participate (Figure 1). A total of 202 patients were randomized, with a median age of 65 years; 22.8% were women, 90.6% classified as NYHA class II (Table 1). Complete primary outcome data were available for 186 patients, representing 92.1% (Table S1). A CONSORT (Consolidated Standards of Reporting Trials) flowchart detailing the trial's progression is provided in Figure 1. Major and minor protocol violations are detailed in Table S2.

Adherence to Intervention

Of the 101 patients allocated to the intervention group, 19 did not adhere to the prespecified criteria: 3 patients declined to wear the activity tracker immediately after randomization, another 3 declined to wear the activity tracker later during the intervention period, 7 missed their clinic visits at either 3 or 6 months, and 14 participated in fewer than 3 of the 5 planned counseling sessions. As a result, 82 patients (81%) fully adhered to the intervention.

Of the 84 patients in the intervention group who participated in at least 3 of the 5 planned counseling sessions and did not decline to wear the tracker, 70 (83%) consistently kept their diaries, and 77 (92%) consistently provided estimates of their recent step counts during all telephone contacts.

Primary Outcome

In the intention-to-treat analysis of the complete cases, the intervention effect on the 6MWT at 6 months was +7.4 meters (95% CI, -8.0 to 22.7; *P*=0.345). The supplementary analysis after the imputation of missing cases and the per-protocol analysis yielded similar results (Table 2).

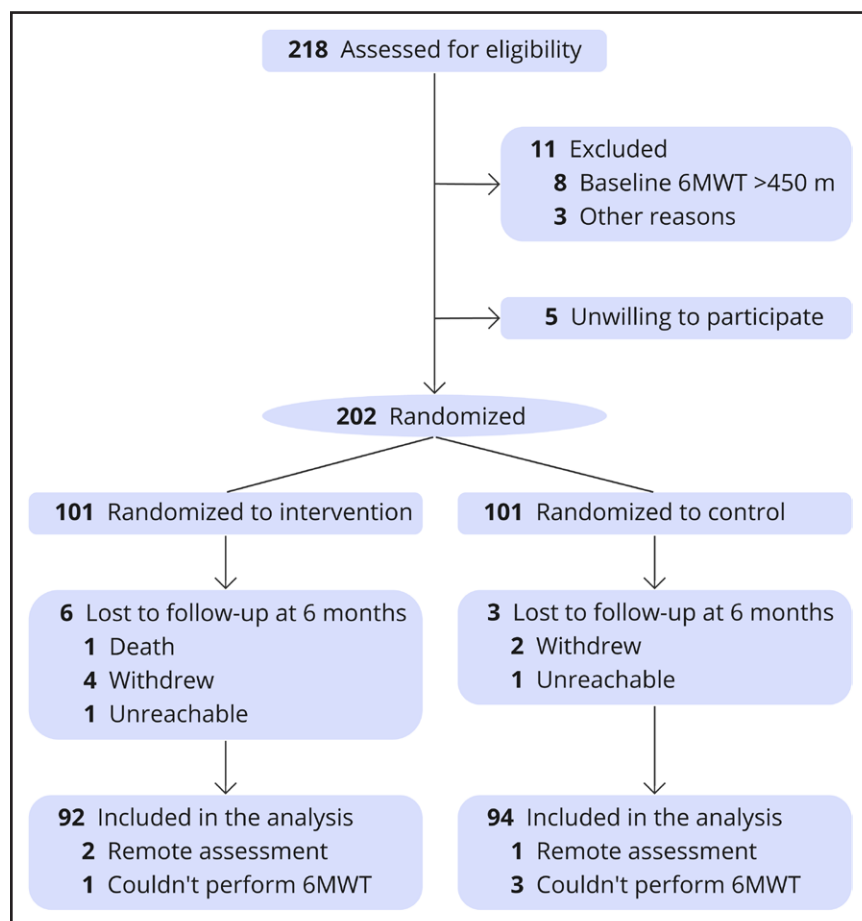


Figure 1. Study enrollment, randomization, and follow-up. 6MWT indicates 6-minute walk test.

Table 1. Baseline Characteristics

Characteristics	All patients (n=202)	Intervention group (n=101)	Control group (n=101)
Age at time of randomization, y	65.0 (56.0–72.8)	65.0 (56.0–72.0)	65.0 (56.0–73.0)
Sex			
Male	156 (77.2)	78 (77.2)	78 (77.2)
Female	46 (22.8)	23 (22.8)	23 (22.8)
Marital status			
Married	131 (65.5)	69 (69.7)	62 (61.4)
Divorced	24 (12.0)	10 (10.1)	14 (13.9)
Single	20 (10.0)	10 (10.1)	10 (9.9)
Widowed	17 (8.5)	8 (8.1)	9 (8.9)
Living with a partner	8 (4.0)	2 (2.0)	6 (5.9)
Education level			
Elementary	16 (8.0)	7 (7.1)	9 (8.9)
Secondary	153 (76.9)	73 (74.5)	80 (79.2)
University	30 (15.1)	18 (18.4)	12 (11.9)
Employment status			
Employed	52 (25.9)	31 (31.0)	21 (20.8)
Unemployed	11 (5.5)	4 (4.0)	7 (6.9)
On old age pension	109 (54.2)	55 (55.0)	54 (53.5)
On disability pension	29 (14.4)	10 (10.0)	19 (18.8)
Smoking status			
Never smoked	63 (31.2)	31 (30.7)	32 (31.7)
Ex-smoker	105 (52.0)	55 (54.5)	50 (49.5)
Current smoker	34 (16.8)	15 (14.9)	19 (18.8)
Alcohol intake			
Does not consume	65 (32.2)	33 (32.7)	32 (31.7)
Occasionally consumes	112 (55.4)	55 (54.5)	57 (56.4)
Regularly consumes	25 (12.4)	13 (12.9)	12 (11.9)
Average daily step count	5071 (3148–7357)	4851 (3049–7357)	5343 (3168–7265)
Average daily minutes of MVPA	10.9 (3.2–27.3)	11.1 (3.6–27.3)	10.2 (2.6–27.7)
Distance walked during the 6MWT, m	385.0 (329.0–425.0)	390.0 (325.0–430.0)	371.0 (329.8–420.0)
Systolic blood pressure, mm Hg	120.0 (109.0–130.0)	120.0 (109.0–130.0)	120.0 (110.0–131.0)
Diastolic blood pressure, mm Hg	77.0 (70.0–80.0)	78.0 (69.0–80.0)	77.0 (70.0–80.0)
Body mass index, kg/m ²	29.0 (25.8–33.4)	29.7 (26.0–33.6)	28.5 (25.1–33.0)
Waist circumference, cm	107.0 (97.0–118.0)	109.0 (99.0–118.0)	104.0 (96.8–117.2)
NYHA class			
II	183 (90.6)	92 (91.1)	91 (90.1)
III	19 (9.4)	9 (8.9)	10 (9.9)
Left ventricular ejection fraction, %	32.5 (25.0–36.8)	34.0 (26.0–37.0)	32.0 (25.0–36.0)

(Continued)

Table 1. Continued

Characteristics	All patients (n=202)	Intervention group (n=101)	Control group (n=101)
NT-proBNP, ng/L	597.0 (287.0–1483.0)	597.0 (276.0–1483.0)	613.5 (293.5–1480.0)
hsCRP, mg/L	2.1 (1.0–5.3)	1.9 (1.0–4.8)	2.3 (1.1–5.4)
Creatinine, μmol/L	93.0 (79.2–113.8)	93.0 (79.5–115.5)	93.0 (79.5–110.5)
eGFR <60 mL·min ⁻¹ ·73 m ²	78 (38.6)	42 (41.6)	36 (35.6)
Ischemic heart disease			
Yes	121 (59.9)	67 (66.3)	54 (53.5)
No	81 (40.1)	34 (33.7)	47 (46.5)
MAGGIC score	19.0 (5.7)	18.6 (5.7)	19.5 (5.7)
Comorbidities			
Arterial hypertension	128 (63.4)	65 (64.4)	63 (62.4)
Previous myocardial infarction	96 (47.5)	51 (50.5)	45 (44.6)
History of atrial fibrillation or flutter	63 (31.2)	33 (32.7)	30 (29.7)
Atrial fibrillation or flutter at screening	23 (11.4)	13 (12.9)	10 (9.9)
Peripheral artery disease	21 (10.4)	9 (8.9)	12 (11.9)
History of cardiac arrest	19 (9.4)	9 (8.9)	10 (9.9)
Stroke	15 (7.4)	8 (7.9)	7 (6.9)
Valve procedure	13 (6.4)	4 (4)	9 (8.9)
Type 2 diabetes	78 (38.6)	37 (36.6)	41 (40.6)
COPD	21 (10.4)	13 (12.9)	8 (7.9)
Depression	16 (7.9)	10 (9.9)	6 (5.9)
Bronchial asthma	12 (5.9)	4 (4)	8 (7.9)
History of malignancy	11 (5.4)	6 (5.9)	5 (5)
Device therapy			
ICD or CRT-D	114 (56.4)	57 (56.4)	57 (56.4)
CRT-P or CRT-D	52 (25.7)	31 (30.7)	21 (20.8)
Medication			
β-blocker	195 (96.5)	99 (98)	96 (95)
ARNI	114 (56.4)	58 (57.4)	56 (55.4)
ACEi	63 (31.2)	32 (31.7)	31 (30.7)
ARB	16 (7.9)	8 (7.9)	8 (7.9)
MRA	159 (78.7)	78 (77.2)	81 (80.2)
SGLT2i	37 (18.3)	17 (16.8)	20 (19.8)
Loop diuretics	160 (79.2)	77 (76.2)	83 (82.2)
Digoxin	27 (13.4)	13 (12.9)	14 (13.9)
Ivabradine	18 (8.9)	7 (6.9)	11 (10.9)

Values are median (interquartile range), n (%), or mean (SD). 6MWT indicates 6-minute walk test; ACEi, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; COPD, chronic obstructive pulmonary disease; CRT-D, cardiac resynchronization therapy–defibrillator; CRT-P, cardiac resynchronization therapy–pacemaker; eGFR, estimated glomerular filtration rate; hsCRP, high-sensitivity C-reactive protein; ICD, implantable cardioverter defibrillator; MAGGIC, Meta-Analysis Global Group in Chronic Heart Failure risk score; MRA, mineralocorticoid receptor antagonist; MVPA, moderate to vigorous physical activity; and SGLT2i, sodium-glucose cotransporter 2 inhibitor.

Table 2. Analyses of the Primary Outcome (6-Minute Walk Test) at 6 Months

Analysis (number of patients included in the analysis)	Intervention group				Control group				Adjusted between-group difference (95% CI)	P value
	Value at baseline, median (IQR)	Value at 6 months, median (IQR)	Change, median (IQR)	Change, mean (95% CI)	Value at baseline, median (IQR)	Value at 6 months, median (IQR)	Change, median (IQR)	Change, mean (95% CI)		
Intention-to-treat analysis of the complete cases (n=186)	388.0 (324.2, 427.0)	417.5 (375.5, 475.5)	40.0 (0.0, 70.0)	35.5 (22.7, 48.3)	373.5 (331.0, 420.0)	400.0 (357.0, 450.0)	34.5 (0.0, 53.8)	28.8 (18.6, 39.0)	7.4 (−8.0, 22.7)	0.345
Intention-to-treat analysis following the imputation of missing cases (n=202)	390.0 (325.0, 430.0)	420.0 (358.0, 474.0)	38.0 (5.0, 70.0)	35.2 (23.5, 47.0)	372.0 (330.0, 420.0)	400.0 (350.0, 450.0)	31.0 (−4.4, 53.0)	26.9 (17.2, 36.5)	8.7 (−5.6, 22.9)	0.231
Per-protocol analysis (n=137)	394.0 (330.0, 430.0)	420.0 (374.0, 477.0)	40.0 (2.5, 70.0)	37.1 (21.3, 52.9)	382.5 (331.0, 420.0)	401.5 (365.0, 453.8)	36.0 (−0.0, 58.5)	30.1 (18.9, 41.2)	5.7 (−12.6, 24.0)	0.539

Change in the 6-minute walk test was not normally distributed. IQR indicates interquartile range.

Secondary Outcomes

In the intention-to-treat analysis of secondary outcomes at 6 months (Table 3), notable findings include the positive intervention effect on average daily step count (+1420 [95% CI, 749 to 2091]) and minutes of MVPA (+8.2 [95% CI, 3.0 to 13.3]). Results for the intention-to-treat analysis at 3 months are reported in Table S3. Per-protocol analyses at 6 months (Table S4) and 3 months (Table S5) produced similar results as those conducted by intention to treat.

Subgroup Analyses

In the exploratory subgroup analyses of the primary outcome, no significant differences between the subgroups were observed (Figure 2), although there was a numeric improvement in younger, nonobese patients with better functional status and milder disease severity.

Adverse Events

Adverse events for each trial group are detailed in Table 4, where the number of occurrences for each event is presented separately for each trial group. The most frequently recorded adverse events were cardiovascular events, including hospitalization for cardiovascular reasons (13 patients). Five patients either visited the emergency department or were hospitalized because of HF decompensation and 4 patients required an increased diuretic dose. No adverse events directly related to the intervention were reported.

DISCUSSION

In this randomized controlled trial of a 6-month walking intervention in patients with stable HFrEF, no significant improvement in the primary outcome of 6MWT distance was observed. Among the secondary outcomes, both objective PA measures (step count and time in MVPA) showed significant improvements, as did self-reported general health score, but there were no significant dif-

ferences in levels of NT-proBNP or high-sensitivity C-reactive protein, ejection fraction, anthropometric measures, depression scores, self-efficacy, most domains of quality of life, or survival risk scores.

The observed improvement in PA by 1420 steps/day—representing an ≈25% increase—is substantial and equivalent to cardiac rehabilitation studies in cardiovascular patients.²⁰ It also aligns with findings from other trials evaluating various PA interventions across a range of populations and settings, including patients with chronic conditions²³ as well as healthy²¹ and older²² adults in community settings. In cohort studies with long-term follow-up, the difference of just 1000 steps per day has been associated with a significant decrease in all-cause mortality rate by 15% in both the general population⁴⁰ and patients with HF.⁴¹ Furthermore, the minimum clinically important difference for the physically inactive general population⁴² as well as patients with chronic conditions such as chronic obstructive pulmonary disease⁴³ or peripheral artery disease⁴⁴ has been estimated to lie between 500 and 1100 steps per day. Thus, it is noteworthy that despite successfully enhancing PA levels, our intervention did not yield a corresponding improvement in functional capacity assessed by the 6MWT.

A plausible explanation for this disconnection could be that despite a substantial increase in the volume of PA as indicated by step count, the pattern, duration, and intensity of PA were insufficient to elicit changes in the 6MWT.^{30,45} Indeed, most cardiac rehabilitation studies showing improvement in 6MWT for patients with HFrEF used supervised, structured exercises with rigorously prescribed duration and intensity.^{8,31} In contrast, our lifestyle walking intervention was more natural, solely focused on increasing the daily number of steps; it was intentionally neither supervised nor structured, and did not require specific duration and intensity of PA. As a result, patients in our study could accumulate additional steps in very short bouts and at low intensities, differing from the approach of exercise-based rehabilitation programs, which typically prescribe walking or other exercise modalities in bouts of at least 20 minutes at an intensity >60% of heart rate reserve.^{8,26,46–48} Our study observed

Table 3. Intention-to-Treat Analysis of the Secondary Outcomes at 6 Months

Outcome (number of patients with complete data)	Change in intervention group, median (IQR)	Change in intervention group, mean (95% CI)	Change in control group, median (IQR)	Change in control group, mean (95% CI)	Adjusted between-group difference (95% CI)
Average daily step count (n=131)	631.4 (−617.1, 1639.2)	790 (332, 1247)	−488.0 (−1899.3, 728.7)	−667 (−1183, −152)	1420 (749, 2091)
Average daily minutes of MVPA (n=131)	0.4 (−3.3, 9.5)	4.9 (1.0, 8.7)	−0.5 (−7.1, 1.5)	−3.1 (−6.8, 0.6)	8.2 (3.0, 13.3)
NT-proBNP, ng/L (n=190)	−23.0 (−260.0, 162.0)	114 (−370, 598)	−35.0 (−321.0, 155.0)	−220 (−516, 75)	349 (−193, 892)
hsCRP, mg/L (n=126)	0.0 (−0.6, 0.8)	1.7 (−0.9, 4.2)	−0.1 (−1.5, 0.5)	−0.3 (−2.2, 1.7)	2.1 (−1.0, 5.1)
LVEF, % (n=189)	2.0 (0.0, 6.0)	3.9 (2.5, 5.4)	3.0 (−0.3, 9.0)	3.7 (2.4, 5.0)	0.3 (−1.5, 2.2)
BDI-II (n=177)	−1.0 (−3.0, 1.0)	−0.7 (−1.6, 0.1)	0.0 (−2.0, 1.0)	0.1 (−0.8, 1.0)	−0.8 (−1.9, 0.4)
SF-36: Physical functioning (n=177)	0.0 (−5.0, 10.0)	1.3 (−1.3, 4.0)	0.0 (−5.0, 10.0)	0.2 (−2.9, 3.3)	1.3 (−2.5, 5.2)
SF-36: Role–Physical (n=177)	0.0 (0.0, 25.0)	3.5 (−4.0, 10.9)	0.0 (−25.0, 0.0)	−4.7 (−12.4, 3.0)	8.3 (−1.3, 17.8)
SF-36: Bodily pain (n=177)	0.0 (−20.0, 12.5)	−4.1 (−10.0, 1.8)	0.0 (−10.0, 10.0)	0.3 (−3.4, 4.0)	−4.9 (−11.0, 1.2)
SF-36: General health (n=177)	5.0 (−3.8, 15.0)	6.3 (3.2, 9.4)	0.0 (−5.0, 10.0)	1.3 (−2.0, 4.5)	4.5 (0.7, 8.4)
SF-36: Vitality (n=177)	0.0 (−5.0, 10.0)	2.6 (−0.2, 5.3)	0.0 (−10.0, 10.0)	−0.5 (−3.3, 2.2)	2.4 (−1.3, 6.0)
SF-36: Social functioning (n=177)	0.0 (−12.5, 12.5)	−1.2 (−5.6, 3.3)	0.0 (−12.5, 12.5)	−1.8 (−5.7, 2.1)	0.5 (−4.9, 5.9)
SF-36: Role–Emotional (n=177)	0.0 (0.0, 33.3)	8.9 (0.7, 17.1)	0.0 (0.0, 0.0)	0.7 (−7.3, 8.8)	4.3 (−5.0, 13.7)
SF-36: Mental health (n=177)	0.0 (−8.0, 4.0)	−1.2 (−4.2, 1.8)	0.0 (−8.0, 4.0)	−1.6 (−3.9, 0.6)	0.8 (−2.7, 4.3)
GSE (n=177)	0.0 (−2.5, 3.5)	0.2 (−1.0, 1.3)	0.0 (−2.0, 2.0)	−0.2 (−1.7, 1.3)	0.5 (−1.1, 2.1)
Weight, kg (n=193)	0.0 (−2.0, 2.0)	0.1 (−0.7, 1.0)	1.0 (−0.8, 3.0)	1.1 (0.3, 1.9)	−1.0 (−2.1, 0.1)
Waist circumference, cm (n=190)	0.0 (−2.0, 2.0)	−0.3 (−1.2, 0.5)	0.0 (−1.0, 3.0)	1.8 (−0.5, 4.2)	−1.5 (−3.7, 0.8)
Hip circumference, cm (n=190)	0.0 (−2.0, 2.0)	0.0 (−1.3, 1.2)	0.0 (−1.0, 3.0)	1.9 (−0.4, 4.1)	−0.9 (−3.1, 1.3)
MAGGIC risk score (n=189)	−1.0 (−2.0, 1.0)	−0.5 (−1.1, 0.0)	−1.0 (−3.0, 0.0)	−1.1 (−1.7, −0.5)	0.4 (−0.4, 1.2)

None of the changes in variables followed a normal distribution. BDI-II indicates Beck Depression Inventory II; GSE, General Self-Efficacy Scale; hsCRP, high-sensitivity C-reactive protein; LVEF, left ventricular ejection fraction; MAGGIC, Meta-Analysis Global Group in Chronic Heart Failure risk score; MVPA, moderate to vigorous physical activity; and SF-36, 36-item Short-Form Health Survey.

an increase of 8 minutes of MVPA per day—equivalent to ≈800 steps—indicating that the intervention group did achieve some of their additional PA at higher intensities. However, the use of minutes of MVPA as a cut point—based measure has inherent limitations,⁴⁹ leaving it uncertain whether the patients reached the intensities typically prescribed in exercise-based cardiac rehabilitation programs.^{26,30,48}

An alternative explanation might be that the baseline 6MWT distance of 385 meters was near the patients' maximum potential for improvement, suggesting a possible ceiling effect.⁵⁰ However, this hypothesis is not supported by our exploratory analysis, which compared subgroups of patients below and above the median baseline 6MWT. Patients above the median exhibited greater improvements in 6MWT. This underscores the importance of initial functional capacity in interpreting

the potential benefits of interventions on 6MWT outcomes. Another conceivable explanation could be the relatively high initial PA levels of the participants. The benefits of an increased step count are most pronounced in individuals who are the least active, typically averaging ≈3000 steps per day.⁵¹ In contrast, our participants had a baseline of ≈5000 steps, representative of the step count observed in patients with HF in other studies.⁵² Nonetheless, this explanation seems less plausible, as our subgroup analysis revealed that patients with step counts above the median tended to benefit more from the intervention compared with those below the median. Another explanation could be the COVID-19 pandemic, which significantly affected patients' activity levels and could have confounded the results.⁵³ Exploratory subgroup analysis indicated that patients who participated before the onset of the pandemic experienced greater

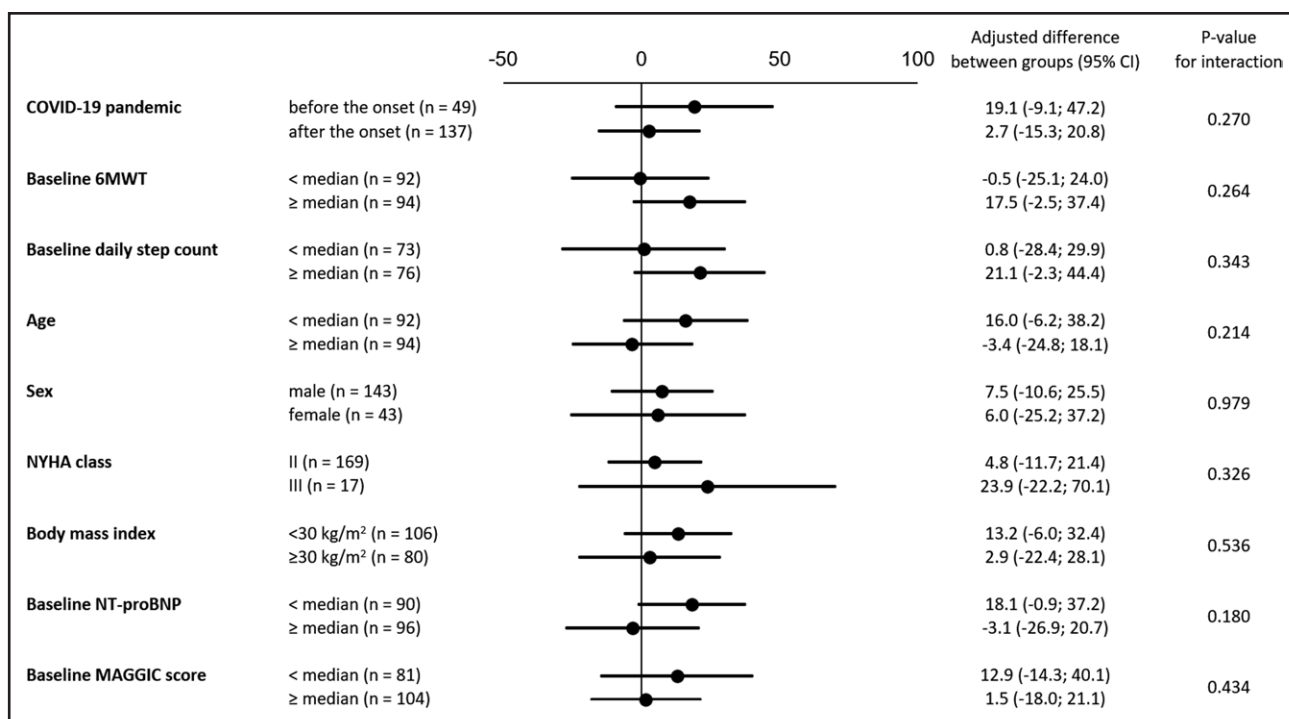


Figure 2. Subgroup analyses of the primary outcome (6-minute walk test) at 6 months.

(albeit insignificantly) gains in 6MWT than those who participated after the onset. Nonetheless, the improvement of 19 meters in the former group was still considerably below the minimal clinically important difference. Therefore, although the COVID-19 pandemic may have had some influence, it is unlikely to fully explain the observed lack of significant improvement in 6MWT in our study.

Results in Context of Other Literature

A limited number of studies have investigated the effect of interventions aiming to enhance the PA of patients with HF in everyday life outside of structured exercise-based programs, with the majority showing limited success.^{6,13} For instance, the REACH-HF trial, which incorporated a progressive walking program, did not result in elevated PA levels overall or show any between-group difference in the incremental shuttle walk test, although it did show improvement in disease-specific health-related quality of life, its primary outcome.⁵⁴ The HF-Wii trial adopted a different approach, using home-based exergaming to encourage increased PA in patients with HF. The intensity of the exergames varied from 2.0 to 4.2 metabolic equivalents, but most participants opted for the lower-intensity games. After adjusting for baseline 6MWT, the trial found no significant differences in the 6MWT, leading the authors to conclude that the intervention might not have been sufficiently intense,⁵⁵ similar to our results.

In contrast to the aforementioned lifestyle PA interventions, the results from structured exercise-based programs have demonstrated significant improvements

in both the 6MWT^{30,56} and quality of life.^{57,58} Nevertheless, even in these trials, the improvements observed in the 6MWT are often modest and tend to be short-term. For example, the individual participant meta-analysis EXTRAMATCH II (Exercise Training Meta-Analysis of Trials for Chronic Heart Failure) reported improvements in the 6MWT at 12-month follow-up of 21 meters.⁵⁹ Moreover, HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training), the largest trial of exercise-based rehabilitation to date, identified a significant intervention effect of 15 meters at 3 months, but this effect disappeared at 12 months.⁸ Furthermore, a recent large 9-week telerehabilitation trial, TELEREH-HF (Telerehabilitation in Heart Failure Patients), found a significant difference in the 6MWT of only 9 meters.³¹ Our trial was not powered to detect such small differences in the 6MWT, and it is debatable whether these differences are clinically relevant.²⁹

Strengths and Limitations

Our study has several important strengths. First, our recruitment strategy drew from a range of centers across the Czech Republic, enhancing generalizability. Second, our participants' average baseline step count was representative of patients with HF as observed in other studies,⁴³ further bolstering external validity. Third, we used objective assessment methods for PA, using accelerometers, which minimized subjective bias and provided accurate and reliable data on participants' activity levels. Last, our study exhibited minimal losses to follow-up, with only an 8%

Table 4. Adverse Events

Adverse event category	All patients (n=202)	Intervention group (n=101)	Control group (n=101)
Hospitalization for heart failure	4	1	3
Visit to the emergency department for heart failure	1	0	1
Increase in diuretic dose	4	1	3
Other cardiovascular events including hospitalizations for cardiovascular reasons	13	5	8
Noncardiovascular events including hospitalizations for noncardiovascular reasons	9	8	1
ICD discharge	6	4	2
Fall, injury	2	0	2
Infection	9	5	4
Others	3	2	1
Death	1	1*	0
Total	52†	27	25

ICD indicates implantable cardioverter defibrillator.

*The only death was from a noncardiovascular cause.

†In total, 52 adverse events were recorded in 42 patients.

dropout rate, thereby reducing the risk of attrition bias and ensuring a comprehensive analysis of the collected data. These strengths collectively contribute to the robustness and real-world applicability of our study findings.

Several limitations warrant consideration and may influence the interpretation of the findings. First, our study was designed to detect a clinically meaningful change of 45 meters in the 6MWT. However, smaller changes that might still be of clinical significance could have been missed. Furthermore, the observed between-group difference of 1420 steps might not have been substantial enough to elicit a 45-meter improvement in the 6MWT. A study powered to detect smaller 6MWT differences, while also achieving more pronounced step count increases, might discern a significant effect on the 6MWT. In addition, the study might not have been powered to detect differences in secondary outcomes. Second, the follow-up period of 6 months might not be sufficient to observe the long-term effects of the intervention on functional capacity and other outcomes. The ongoing 12-month follow-up will provide more insights into the long-term sustainability of the observed changes in PA. Third, for practical reasons, we could not record the number and characteristics of all patients who were considered for inclusion but did not enter the formal screening using the baseline 6MWT. Fourth, our study population included a notable proportion of patients with NYHA functional class II and higher baseline 6MWT, which might not be entirely reflective of

the broader HF_rEF population in more recent clinical trials. This could limit the generalizability of our findings to populations with more pronounced functional limitations. Fifth, because of constraints of the study design and to ensure a manageable assessment burden on participants, the study did not include HF-specific patient-reported outcomes such as the Kansas City Cardiomyopathy Questionnaire or the Minnesota Living with Heart Failure Questionnaire, which might have offered a more nuanced assessment of the patients' quality of life in the context of HF. Sixth, the absence of patient blinding constitutes an important limitation. Being aware of their group assignment could potentially influence participants' behavior, especially during assessments, thereby introducing bias into the reported outcomes.

Conclusions

Integrating a simple lifestyle walking intervention into the daily life of patients with stable HF_rEF did not improve their functional capacity, despite having increased their objectively measured PA levels. Achieving improvements in functional capacity likely necessitates the implementation of traditional supervised, structured exercise-based rehabilitation programs with specified durations and intensities. As these programs often fail to induce sustained behavioral change in the long term, future studies should explore the potential of a comprehensive approach that combines exercise-based rehabilitation with simple lifestyle PA interventions, using tools such as activity trackers and mobile apps, to support long-term behavioral change and enhance health outcomes of patients with HF_rEF.

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Disclosures

Dr Belohlavek reports receiving lecture honoraria and participation on advisory boards for Novartis, Boehringer Ingelheim, and AstraZeneca. Dr Linhart reports receiving lecture honoraria and participation on advisory boards for Novartis, Boehringer Ingelheim, and AstraZeneca. Dr Vesely reports receiving lecture honoraria and participation on advisory boards for Novartis, Boehringer Ingelheim, and AstraZeneca. Dr Svobodova reports receiving lecture honoraria from Novartis, Boehringer Ingelheim, and AstraZeneca and participation on an advisory board for Boehringer Ingelheim. Dr Pelouch reports receiving lecture honoraria from Novartis, Boehringer Ingelheim, and AstraZeneca. The other investigators report no conflicts of interest.

Supplemental Material

Appendices 1–4
Tables S1–S5

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