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Usefulness of a Lifestyle Intervention in Patients With Cardiovascular Disease

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The importance of modifying lifestyle factors in order to improve prognosis in cardiac patients is well-known. Current study aims to evaluate the effects of a lifestyle intervention on changes in lifestyle- and health data derived from wearable devices. Cardiac patients from Spain (n = 34) and The Netherlands (n = 36) were included in the current analysis. Data were collected for 210 days, using the Fitbit activity tracker, Beddit sleep tracker, Moves app (GPS tracker), and the Careportal home monitoring system. Locally Weighted Error Sum of Squares regression assessed trajectories of outcome variables. Linear Mixed Effects regression analysis was used to find relevant predictors of improvement deterioration of outcome measures. Analysis showed that Number of Steps and Activity Level significantly changed over time ($F = 58.21$, $p < 0.001$; $F = 6.33$, $p = 0.01$). No significant changes were observed on blood pressure, weight, and sleep efficiency. Secondary analysis revealed that being male was associated with higher activity levels ($F = 12.53$, $p < 0.001$) and higher number of steps ($F = 8.44$, $p < 0.01$). Secondary analysis revealed demographic (gender, nationality, marital status), clinical (co-morbidities, heart failure), and psychological (anxiety, depression) profiles that were associated with lifestyle measures. In conclusion results showed that physical activity increased over time and that certain subgroups of patients were more likely to have a better lifestyle behaviors based on their demographic, clinical, and psychological profile. This advocates a personalized approach in future studies in order to change lifestyle in cardiac patients. **(Am J Cardiol 2020;125:370−375)**

Cardiovascular diseases are the leading cause of death globally.[1] It is well known that modifiable (behavioral) risk factors (eg, sedentary lifestyle, low sleep efficiency) are associated with increased mortality risk and disease progression.[1] Hence, the implementation of effectual lifestyle interventions within this population might contribute to better health outcomes, and reduce the economic and healthcare burden of cardiovascular diseases.[2] In order to reach this goal, cost-effective, technology based approaches may be the way forward[3] as they have shown promising results with respect to changes in a variety of unhealthy lifestyle behaviors (eg, physical activity,[4] sleep efficiency,[5] blood pressure regulation[6]). As compared with traditional, self-report measures, wearable (consumer) sensors provide opportunities to assess lifestyle behavior patterns in a more accurate and ecological valid manner.[7,8] Hence, current study aims to (1) evaluate changes in objectively measured lifestyle- and health data derived from wearable devices and (2) examine which demographic, psychosocial, and clinical predictors are associated with improvement/deterioration of these measures.

Methods

The current study was part of an international, multicenter randomized controlled trial, the Do Cardiac Health Advanced New Generation Ecosystem 2 (Do CHANGE 2− NCT03178305) study. This trial was primarily designed to evaluate a multicomponent digital intervention on lifestyle change in cardiac patients that is described in more detail elsewhere.[9]

Current sample is constituted from patients diagnosed with hypertension (HT) (values ≥140 mmHg of systolic blood pressure and/or ≥90 of diastolic blood pressure in 2 different measurements spaced 1 to-2 minutes apart and after 3 to 5 minutes in a sitting position), symptomatic heart failure (HF) (New York Heart Association Class I-IV), or coronary artery disease (CAD) (having experienced angina pectoris, a myocardial infarction, percutaneous coronary intervention and/or coronary artery bypass), who were recruited between June 2017 and December 2017 in Spain and the Netherlands. Exclusion criteria existed of not having access to the Internet or a compatible smartphone, having insufficient knowledge of the local language (ie, Spanish, Dutch), suffering from life-threatening co-morbidities

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See page 374 for disclosure information.

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(eg, malignancy), cognitive impairment, a life expectancy of <1 year, on the waiting list for heart transplantation, or having a history of psychiatric illness other than affective/anxiety disorders.

Eligible patients who agreed to participate received a baseline questionnaire and an informed consent form at home and were requested to send these back within 10 working days. After receiving the informed consent form and baseline questionnaire, randomization (2:2) took place. Information about the devices (eg, Fitbit, Beddit, Careportal monitoring) was provided to patients in the intervention group during a scheduled outpatient clinic visit. All participants were asked to fill out follow-up questionnaires at 3 and 6 months after baseline measurement and were requested to send these back within 2 weeks. Only patients randomized to the intervention group were analyzed for current study, because of the availability of sensor data. They were asked to use the Fitbit, Beddit, and Careportal daily over a period of 6 months (210 days).

Randomization (2:2) to either the intervention or usual care group took place after receiving both the signed informed consent form and the questionnaire. An independent researcher generated and sealed computerized randomization sequences in stacks of 4 before recruitment started. Group allocation was determined by drawing a sealed envelope per patient by the research assistant. Blinding participants or healthcare providers was not possible due to the nature of the study.

The study protocol was approved by Medical Ethics Committee (METC-Brabant − NL61660.028.17/P1726) in the Netherlands and is in line with the Helsinki declaration.

Baseline clinical (Charlson Comorbidity Index (CCI), main diagnosis (HT, CAD, HF)) and demographic (age, gender, marital status, site of inclusion, anxiety, depression, Type D personality) characteristics were assessed by reviewing patients' medical records and purpose-designed self-report questionnaires.

Data sources were aggregated using the Do CHANGE platform,[10,11] to securely collect and distribute data from 3rd party vendors to consortium partners.

Data on physical activity and number of steps was collected by a personal Fitbit smartwatch.[12] In case data on physical activity from Fitbit was unavailable, it was imputed by data from the Moves GPS app that was installed on patients' mobile phone. However, due to its better accuracy, physical activity data from Fitbit was preferred. The physical activity score was the estimate of the general activity over the day (combination of length of active periods and number of steps). The higher the score, the higher the physical activity.

Data on sleep efficiency was derived by a Beddit 3 sleeptracker.[13] This device is certified to measure breathing, sleep, and heart rate. The Beddit uses ballistocardiography to measure minute movements in the body resulting from breathing and a heartbeat. The input signal is subjected to several processing steps to filter out the breathing frequency, breathing intensity, heart rate, and various other parameters.

The UA − 767 Plus digital blood pressure monitor was used in order to measure systolic and diastolic blood pressure on a daily basis. Blood pressure levels were logged into the Careportal by patients themselves.

Participants from the 3 diagnosis groups recorded weight readings on a daily basis. Only HF patients received a Seca Aura 807 weight scale, because of the disease specific symptoms. Patients with CAD or HT used their own weight scale at home. Weight was inserted into the Careportal on a daily basis.

Questionnaires at baseline included the DS-14 for Type D personality,[14] the GAD-7 for symptoms of anxiety,[15] and the PHQ9 for symptoms of depression.[16]

Descriptive statistics were calculated for the total intervention group, and displayed based on country of inclusion. Normally distributed continuous variables are presented as means ± SD and categorical variables as percentages. The Shapiro-Wilk test normality test was performed to decide whether a continuous variable was normally distributed. In case of a non-normal distributed continuous variable, this was described with median and interquartile range. Categorical variables were described using the Pearson's Chi-squared test.

To obtain more robust results, the statistical analysis was performed on the weekly summarized value of each outcome variable. For the number of steps independently, its weekly summarized value was computed as the sum of all daily values. The nonparametric Locally Weighted Error Sum of Squares (LOESS) regression was applied in order to assess the trajectories of the outcome variables over time. This analysis fits a set of local regression lines that connect in order to draw a fluid line. Mean comparison methods were applied to assess (a) the change in the physical outcome variables in relation to baseline and (b) the change in the physical outcomes variables with regard to country (Spain or The Netherlands). In both cases, the nonparametric Wilcoxon test was applied. Linear Mixed-Effects (LME) modeling was applied to model the overall change of the physical outcome variables (Model 1) over the 6 month follow up, as well as to determine the effect of covariates (ie, age, gender, marital status, culture (country of inclusion), Type D, depression, anxiety, CCI, main diagnosis) on these physical outcome variables (Model 2) over 6 months. p Values smaller than 0.05 are considered statistically significant.

Results

A total of 557 patients from Spain and The Netherlands were approached for participation in the Do CHANGE trial Phase 2.[9] Baseline assessment was filled in by 150 of these patients who were than randomized to either the intervention (n = 76) or the care as usual (n = 74) condition. Only the patients in the intervention group received the devices to monitor their lifestyle- and health parameters. Of the 76 patients who were randomized to the intervention condition, due to drop out (n = 6), 70 patients were included in the current analysis (Spain: n = 34; The Netherlands: n = 36). At baseline, the current results show that patients recruited in Spain were overall younger (p = 0.03), differed in their primary diagnosis from the Dutch sample (p = 0.02), and report higher anxiety levels as compared with patients recruited in The Netherlands (p = 0.02) (Table 1).

When comparing the mean baseline scores with the 12 and 25 week measures, no significant changes in any of the

Table 1
Baseline characteristics stratified by country

Variable	Spain (n = 34)*	The Netherlands (n = 36)*	*p*
Age (in years)	58.8 [43.9; 66.2]	63.3. [57.1; 68.9]	**0.03**
Men	24 (71%)	30 (83%)	0.33
Partner	24 (71%)	32 (89%)	0.05
Smoker	6 (18%)	3 (8%)	0.42
Education (in years)	13.5 [10.0; 18.0]	12.0 [10.0; 16.0]	0.48
Main diagnosis			**0.02**
Hypertension	20 (59%)	10 (28%)	
Coronary artery disease	7 (21%)	18 (50%)	
Heart failure	7 (21%)	8 (22%)	
Charlson Comorbidity Index (≥ 2)	7 (21%)	12 (31%)	0.11
Systolic blood pressure (mmHg)	136.4 ± 19.4	144.2 ± 19.4	0.46
Diastolic blood pressure (mmHg)	79.1 ± 10.0	84.0 ± 9.6	0.37
Depression	4.0 [1.0; 6.0]	3.0 [1.0; 6.0]	0.35
Anxiety	4.0 [2.0; 5.0]	2.0 [0.0; 4.0]	**0.02**
Distressed personality	4 (12%)	6 (17%)	0.81
Received full Do Something Different program	29 (85%)	31 (86%)	1.0

* Note: data are presented as mean [IQR], mean ± SD, or n (%).

outcome variables were observed (results not shown). Applying the Linear Mixed-Effects Modeling (only including Time as a predictor), results revealed that for the variable *Number of Steps* and *Physical Activity* a significant change over time was observed ($F = 59.39$, $p = 0.001$; $F = 6.44$, $p = 0.01$ respectively).

Scores on both *Number of Steps* and *Activity Level* significantly changed over time ($F = 58.21$, $p < 0.001$; $F = 6.33$, $p = 0.01$ respectively) (see Figure 1). For the outcome variable *'Number of Steps'*, the multivariate analysis revealed that male gender was positively associated with the number of steps ($F = 8.44$, $p < 0.01$) while having more co-morbidities (CCI) was associated with a lower number of steps ($F = 7.15$, $p < 0.01$). Patients recruited in The Netherlands also showed a significantly lower number of steps ($F = 13.70$, $p < 0.001$). Patients' *Activity Level* was also positively associated with male gender ($F = 12.53$, $p < 0.001$) and negatively with being recruited in The Netherlands ($F = 5.89$, $p = 0.02$) (Table 2).

Focusing on *Blood Pressure* outcomes, no significant change over time was found for either diastolic ($F = 1.86$, $p = 0.17$) or systolic blood pressure ($F = 3.43$, $p = 0.06$), respectively. Results showed that having heart failure as main diagnosis was associated with lower systolic ($F = 6.09$, $p < 0.01$) and diastolic ($F = 5.47$, $p < 0.01$) blood pressure. Moreover, living together with a partner was also associated with lower diastolic blood pressure ($F = 2.72$, $p = 0.04$). Furthermore, a higher co-morbidity index was associated with higher systolic blood pressure ($F = 7.37$, $p < 0.01$) while being recruited in The Netherlands as associated with higher diastolic blood pressure ($F = 6.98$, $p = 0.01$).

Results with respect to *Weight* showed no significant change over time ($F = 0.36$, $p = 0.55$). Having more co-morbidities ($F = 11.53$, $p < 0.01$), being recruited in The Netherlands ($F = 6.88$, $p = 0.01$), and having higher levels of depressive symptoms ($F = 5.78$, $p = 0.02$) were associated with higher weight. While having higher levels of anxiety symptoms was associated with lower weight ($F = 8.80$, $p < 0.01$).

Finally, results on *Sleep Efficiency* showed also no significant change over time ($F = 2.21$, $p = 0.14$). Older age ($F = 5.44$, $p = 0.02$) and a higher co-morbidity index ($F = 5.37$, $p = 0.03$) were both negatively associated with sleep efficiency.

Discussion

Current study evaluated the effects of a lifestyle intervention for cardiac patients on multiple objectively measured lifestyle- and health data that were collected using wearable devices. The analyses showed significant changes over time in the number of steps and activity level. No significant improvement over time was observed in other outcome measures (ie, blood pressure, weight, and sleep efficiency). Secondary analysis revealed demographic (gender, nationality, marital status), clinical (co-morbidities, heart failure), and psychological (anxiety, depression) profiles that were associated with lifestyle measures.

Current findings are in line with the majority of previous studies that have focused on the use of wearable devices (ie, accelerometers) in cardiac patients.[17,18] However, due to the methodological differences between the studies it is somewhat challenging to compare the results. Current findings show an increase of activity levels at the start of the intervention, and a slow decrease over time. An explanation for this finding could be the discontinuation of the DSD behavioral intervention,[19] and thus the lack of encouraging behavioral prompts between 3 and 6 months after baseline. Furthermore, only the first 3 months of the intervention patients were contacted by phone once a week in order to shortly discuss their health status and last achievements. This might have resulted in feeling more supported and motivated to engage in healthier behavior these first months, suggesting that blended care is the way forward for this patient population.[20] Regarding sleep efficiency, no improvement was observed. The majority of previous studies that found positive associations between lifestyle interventions and (self-reported) sleep quality in cardiac patients

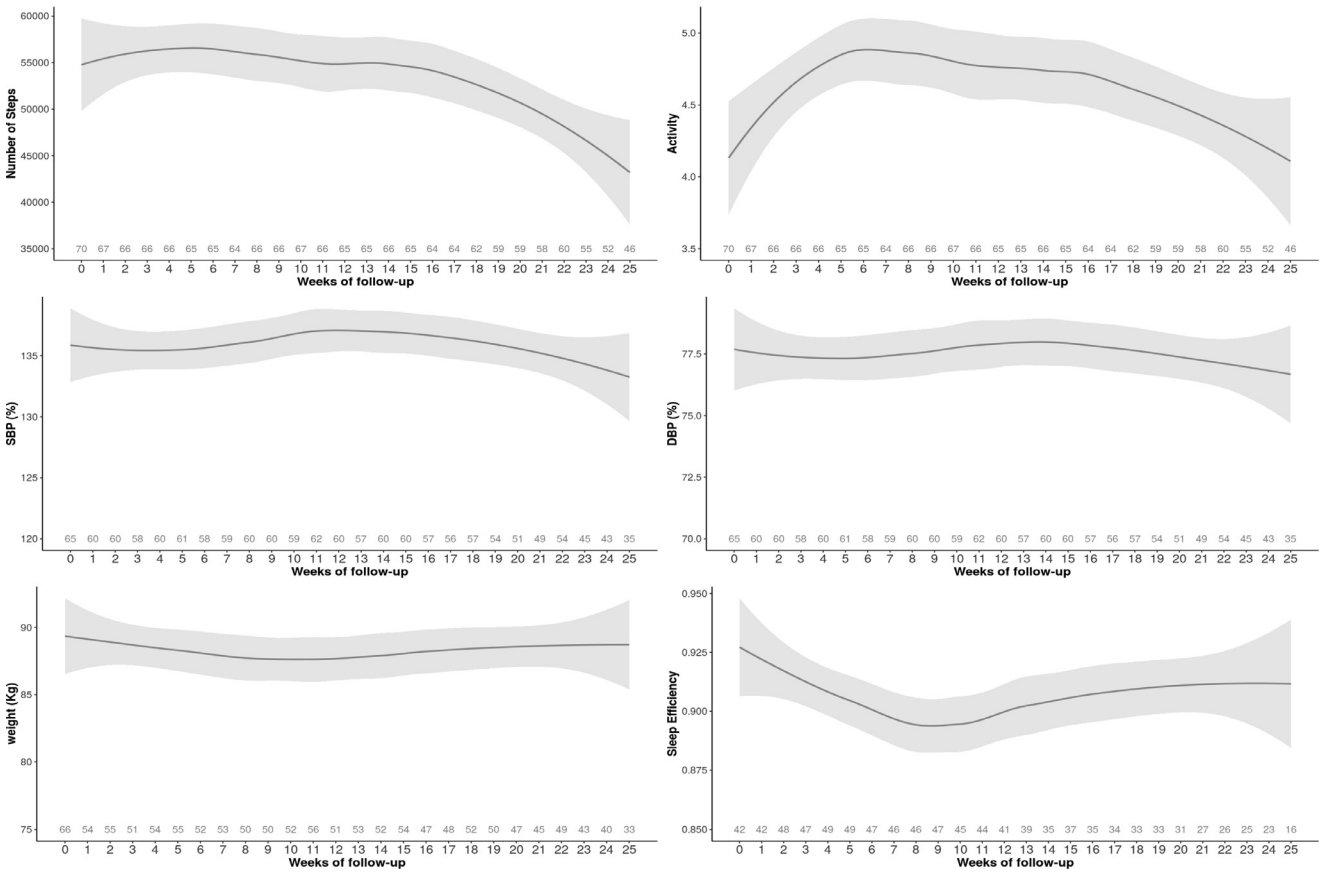

Figure 1. Trends in each outcome variable over the 6 months follow-up.

focused primarily on patients with obesity and established obstructive sleep apnea.[21] Current sample seems to be relatively healthy in this respect. Hence, no room for improvement was to be expected. Furthermore, the unfamiliarity with the Beddit device for participating patients might have influenced the results. As previous research has shown, devices that are already familiar for end-users predict a higher acceptance and utility rate.[22] Another explanation could be the fact that current study focuses on multiple lifestyle behaviors. Sleep is considered as a modifiable lifestyle behavior, but might be a less prominent behavior to change compared with other risk factors (eg, smoking, sedentary behavior).[21] The focus of patients might therefore not be on improving sleep efficiency per se. Moreover, current sample showed a relatively high sleep efficiency rate on average on baseline, leaving little scope for improvement.

As expected, a higher number of co-morbid diseases showed to be related to less favorable objectively measured outcomes, as it significantly predicted a lower number of steps, higher systolic blood pressure, higher weight, and worse sleep efficiency. These findings are in line with previous research that shows that the complex interplay of different co-morbid diseases can impair patients' self-management,[23] and thus may lead to worsening of clinical outcomes. Specific needs and shifting priorities regarding the care for coexistent diseases may be targeted in future interventions to enhance lifestyle behavior change in a personalized manner.[24]

Current findings indicate the importance of a personalized approach. For example, being male was significantly associated with an increase in physical activity levels and step count. This association was also found in a review on socio-ecological correlates of exercise among cardiac patients in rehabilitation settings.[25] Males are more likely to engage in cardiac rehabilitation, as female patients differ in reported individual barriers (eg, family responsibilities) and perceptions (eg, tiring) of exercise.[26] In addition, the need for this personalized approach was also observed regarding culture-related differences in lifestyle behavior. Compared with Spain, being recruited in The Netherlands was a significant predictor of less favorable outcomes. Hence, future research should focus on assessing individual differences and preferences when developing behavioral interventions.

Some limitations should be taken into account. First, current study is a secondary analysis of the Do CHANGE study, which has led to a relatively small sample size without a control condition. Hence, it is not clear whether the results are attributable to the intervention. Second, technological issues (eg, difficulty updating apps due to older mobile phones) may have possibly led to less satisfactory data saturation. Finally, current study only focused on patients using wearable devices. However, in a recent systematic research on the predictors of acceptability of telemedicine in patient populations, Harst[22] stressed the importance of a holistic approach (including partners, healthcare professionals, and institutions) regarding implementation. In addition,

Table 2
LME model likelihood-ratio test (180 days follow up)

Variable	Number of Steps		Activity		Systolic Blood Pressure (mmHg)		Diastolic Blood Pressure (mmHg)		Weight (kg)		Sleep Efficiency	
	F-value	*p*	*F-value*	*p*	*F-value*	*p*	*F-value*	*p*	*F-value*	*p*	*F-value*	*p*
Time	58.21	**<0.001**	6.33	**0.01**	3.43	**0.06**	10.86	0.17	0.36	0.55	2.21	0.14
Time^2	16.90	**<0.001**	26.27	**<0.001**	7.31	**0.007**	2.18	0.14	0.01	0.90	4.65	**0.03**
Age (in years)	0.36	0.55	1.25	0.27	1.07	**0.31**	3.57	0.06	1.88	0.18	5.44	**0.02**
Men	8.44	**0.005**	12.53	**<0.001**	0.16	0.69	1.93	0.17	3.68	0.06	0.55	0.46
Partner	2.28	0.07	2.43	0.06	2.55	0.05	2.72	**0.04**	1.51	0.21	0.55	0.70
Country (Spain)	13.70	**<0.001**	5.89	**0.02**	3.79	**0.06**	6.98	**0.01**	6.88	**0.01**	0.13	0.72
Main diagnosis	1.21	0.30	1.91	0.16	6.09	**0.004**	5.47	0.01	1.51	0.23	1.69	0.20
Charlson Comorbidity Index	7.15	**0.009**	5.33	**0.02**	7.37	**0.01**	2.40	0.13	11.54	**0.001**	5.37	**0.03**
Depression	0.92	0.34	1.77	0.19	3.12	0.08	1.15	0.29	5.78	**0.02**	0.32	0.58
Anxiety	0.44	0.84	0.28	0.60	1.35	0.25	0.14	0.71	8.80	**0.005**	0.17	0.68
Distressed personality	3.27	0.07	2.38	0.13	1.94	0.17	0.001	0.98	2.68	0.11	1.05	0.31
Received full Do Something Different program	0.27	0.61	0.56	0.46	0.09	0.76	0.17	0.69	0.20	0.70	0.001	0.97

this holistic approach could be optimized by assessing and enhancing possible facilitating (psychological) patient characteristics (eg, personality, coping style, and self-efficacy) that could serve as starting-points of more personalized, real-life integrated, and conceivably effective lifestyle interventions. Despite these before mentioned constraints, this is one of the first studies looking at ecologically assessed data of different lifestyle- and health-related measures over a prolonged period of time within the cardiac population.

In conclusion, current study has used a statistical analysis that takes advantage of the informative nature of the multiple data points collected by wearable devices over a prolonged period of time (ie, 210 days). The results showed an improvement in physical activity over time. Secondary analysis showed that certain subgroups of patients are more likely to have better lifestyle behaviors, which advocates that more research is needed in order to disentangle which subgroups of patients might benefit the most from these types of interventions. A personalized approach might be the way forward in order to improve health outcomes in the future.

Disclosures

The authors have no conflicts of interest to disclose.

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Declarations of interest

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Authors' contributions

JW, MW, IA, JPJ, and MH contributed to the conception or design of the work. EB, GG, VR, and MH contributed to the acquisition, analysis, or interpretation of data for the work. EB, GG, and MH drafted the manuscript. EB, GG, JW, MW, VR, IA, JPJ, and MH critically revised the manuscript. All gave approval and agree to be accountable for all aspects of work ensuring integrity and accuracy.

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