

# Cost-effectiveness of telerehabilitation in patients with heart failure in Poland: an analysis based on the results of Telerehabilitation in the Heart Failure Patients (TELEREH-HF) randomized clinical trial

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## A B S T R A C T

**Background:** Telerehabilitation in the Heart Failure Patients (TELEREH-HF) study showed a statistically significant improvement in the tertiary outcomes i.e. the New York Heart Association (NYHA) class after a 9-week follow-up, consistent with telerehabilitation-related benefits to quality of life (QoL) measured with the 36-item Short Form questionnaire (SF-36).

**Aims:** The study analyzed the cost-effectiveness of hybrid telerehabilitation compared to standard care in heart failure patients in the Polish setting using findings from the TELEREH-HF trial.

**Methods:** Cost-utility analysis was conducted from the perspective of a public payer (the Polish National Health Fund). The quality-adjusted life-year (QALY) measure was based on QoL, as survival benefit was not confirmed in the TELEREH-HF. Utility values were estimated based on NYHA improvement and a systematic review of NYHA-specific utility values. Alternatively, SF-36 results were translated into utility values. Telerehabilitation costs covered 8 weeks, 5 days/week, at a daily cost of 74 Polish zloty (PLN). Standard care costs resulted from extra in-patient and out-patient rehabilitation costs incurred for selected patients. A lifetime horizon was adopted, with an estimated average survival time of 3.9 years based on 2 years TELEREH-HF follow-up and subsequent literature-derived prognosis.

**Results:** Base case analysis yielded a 0.044 and 0.027 gain in QALY for the NYHA and SF-36-based approaches, corresponding to a cost per QALY of 58.7 and 96 thousand PLN, respectively. Sensitivity analysis confirmed that the cost per QALY value was likely below the official cost-effectiveness threshold in Poland.

**Conclusions:** The use of telerehabilitation was found cost-effective in Poland, i.e., the clinical benefits justify the additional costs.

**Key words:** cost-effectiveness, heart failure, telerehabilitation

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## INTRODUCTION

Hybrid comprehensive telerehabilitation is the possibility of supervising and providing rehabilitation at a distance by using advanced medical and telecommunication technologies. Telerehabilitation can be combined

with standard cardiovascular rehabilitation programs or used alone as a hybrid comprehensive procedure. High adherence to telerehabilitation may not only improve clinical outcomes but lower total treatment costs of heart failure.

## WHAT'S NEW?

Telerehabilitation in the Heart Failure Patients (TELEREH-HF) randomized clinical trial showed a statistically significant clinical improvement in the tertiary outcomes i.e. the New York Heart Association class, and quality of life of heart failure patients. That benefit justifies the additional cost incurred, and telerehabilitation was found to be a cost-effective intervention in Polish settings.

Therefore telerehabilitation is a feasible and safe alternative to standard rehabilitation [1–3].

The aim of the study was to present a cost-utility analysis (CUA) of a hybrid telerehabilitation procedure in patients with heart failure compared to standard care based on the outcomes of the Telerehabilitation in Heart Failure Patients (TELEREH-HF) randomized clinical trial conducted in 5 Polish centers [4].

The hybrid telerehabilitation program was initiated during hospital stay and continued after discharge in the form of remotely supervised exercise training at home over 8 additional weeks combined with multi-parameter telemonitoring. Patients randomized to the standard care group received usual care appropriate for their clinical status and standardized within a particular center; some of them could participate in a rehabilitation program either in outpatient or inpatient settings [4, 5].

## METHODS

### Type of analysis

The TELEREH-HF trial demonstrated no significant differences between the two groups in overall and cardiovascular mortality [5]. However, there were statistically significant differences in the tertiary outcomes including the New York Heart Association (NYHA) class after 9 weeks in favor of telerehabilitation. This is particularly important as NYHA is more directly related to patients' functioning and quality of life (QoL). In contrast, only small changes in the NYHA class were observed after 9 weeks in those undergoing standard care, with a trend towards a deterioration of the NYHA (Table 1).

Consequently, telerehabilitation may positively impact QoL, even in absence of survival benefit. The outcome was confirmed in a direct comparison of QoL in both groups, which was measured with the 36-item Short Form questionnaire v2 (SF-36). The average score after 9 weeks of care was 91.7 in the telerehabilitation group and 89.3 in the control group ( $P < 0.001$ ).

Due to the QoL differences, a CUA is a suitable comparison technique. For the outcomes of CUA to be a valid basis for financial decisions on health technologies from a single budget, quality-adjusted life years (QALYs) are routinely used to measure the effects [6]. QALYs measure the length of life adjusted for its quality, resulting in what can be thought of as an equivalent of years of life in full health. For various health conditions, the conversion factor of a year spent in a given state to an equivalent of a year in full health is referred to as the health utility [7].

For the health utility to have a theoretical foundation and be economically interpretable, values must be determined through a preference-based method. Thus, the assessment of QoL with the SF-36 cannot be used, as the point values are assigned arbitrarily (e.g., assigning the values of 100, 75, 50, 25, 0 to the levels of a given attribute without checking if the differences between attribute levels are equidistant). Therefore, we converted the data describing a patient's health to a number interpreted as the health utility in order to calculate QALY.

### Perspective

The analysis was conducted from the perspective of a public payer, the Polish National Health Fund (NHF), which seems to be most natural in the context of this study. The patients do not bear the medical costs related to both interventions. Although they can bear additional non-medical costs not covered by the NHF budget and not included in the adopted perspective. Meanwhile, from the perspective of a service provider, the emphasis is placed on the cost-effectiveness of procedure applications (i.e., the differences between the financing provided by NHF and the real costs incurred by the hospital), which are not suitable for making decisions at the level of the entire healthcare system.

### Time horizon and discounting

The lifetime time horizon was selected. Estimation of the average life expectancy (i.e., the horizon under consideration) was performed. Two-year mortality in the TELEREH-HF trial

**Table 1.** The New York Heart Association (NYHA) classification at baseline and after 9 weeks

NYHA class	Telerehabilitation		Standard care	
	Baseline	9 weeks	Baseline	9 weeks
I	51 (13.0)	99 (25.2)	49 (14.2)	60 (14.9)
II	279 (71.0)	242 (61.6)	272 (67.7)	255 (63.4)
III	63 (16.0)	52 (13.2)	81 (20.1)	85 (21.1)
IV	0 (0)	0 (0)	0	2 (0.5)

Data are presented as number (percentage)

**Table 2.** Utility of New York Heart Association (NYHA) classes based on the studies used in the analysis and weighted according to the mean number of patients

	Berg 2015 [11]	Göhler 2009 [12]	Griffiths 2017 [13]	Mean
NYHA I	0.823	0.823	0.823	0.823
NYHA II	0.755	0.752	0.738	0.746
NYHA III	0.673	0.662	0.643	0.657
The number of patients	4147	1395	5313	—

was approximately 12.5% for each group, whereas available studies indicate approximate 75% 5-year mortality in a similar group of patients [8]. Assuming a constant mortality rate in the first 2 years (based on 2-year mortality) and another constant mortality rate in subsequent years (based on the relative probability of survival for 2 years and 5 years, i.e., the probability of surviving 5 years on condition of surviving 2 years), approximate 10-year survival curves were built (by extrapolating the annual risk of death from the 2–5 year to the 5–10 year period). The average survival time estimated (including half-cycle correction) is 3.9 years. This outcome corresponds well with median survival time in patients with heart failure and left ventricular ejection fraction (LVEF) reduced below 40% [8], especially with the assumption of a right-skewed lifetime distribution (i.e., the lifetime of many patients is below average and the lifetime of some patients is substantially above the average — in this case, the mean exceeds the median). Namely, this median is 3.6 years in patients aged 65–69 years and decreases in older age groups (e.g., 2.9 for patients aged 70–74 years and 2.3 for patients aged 75–79 years).

As the time horizon covered by the analysis exceeds one year, discounting was used. A discount rate of 3.5% was adopted [9, 10].

### Population

The outcomes presented in this study refer to the clinical trial population [4]. The TELEREH-HF study was approved by the local Ethics Committee and each patient provided written informed consent.

The majority of patients included in the trial were men (approx. 89%), aged 62 years, and in the NYHA II class (approx. 68%; 20% in NYHA III and 12% in NYHA I).

In the context of the present analysis, it is important that the mean age at enrolment is less than 65–69 years, which is the interval for which the median survival data were presented above. In this sense, the assumption of 3.9 years life expectancy seems conservative, i.e., the actual average life expectancy may exceed 3.9 years.

### Methods of assessing the effects

A CUA was performed, as the TELEREH-HF trial showed benefits of telerehabilitation for tertiary outcomes, suggesting an improvement in QoL. Two outcomes reported in the study were used in the present analysis: the NYHA class and SF-36 QoL assessment. One method was not chosen as a base case due to its complementary nature. The NYHA

class can only take 4 values, which may adversely affect its ability to express the patient's health through the utility accurately. The SF-36 is a generically-used instrument; however, it is more complex, which may be considered a disadvantage as converting the health condition factor to the utility would require the use of more parameters.

Each outcome was converted into the utility. For the NYHA class, a literature review was carried out (see Supplementary material) to evaluate the utility difference between the NYHA classes I and II, I and III, or II and III. Three studies that reported (respectively) large numbers of patients with the LVEF <40% were chosen for the utility parametrization [11–13]. In two of the studies the results were given in the form of utility differences between the NYHA classes (e.g. II and I), not the levels; however, this does not affect the outcome of the CUA as it is only based on utility differences [11, 12]. Nevertheless, to compare the results between studies, the utility level for the NYHA class I was adopted as the value of 0.823 [13]. It is also worth noting that among the studies found in the review, in the present analysis we eventually used those with the largest number of patients. Additionally, the results are very consistent across these studies.

The final data used to assess the utility of the NYHA classes are presented in Table 2. The average baseline utility derived from the NYHA class structure is  $13\% \times 0.823 + 71\% \times 0.746 + 16\% \times 0.657 = 0.7419$ , and is 0.7538 after 9 weeks.

To convert the SF-36 into the utility, the following approach was used. Although state utility sets for the Polish population are available for the health states defined in the EuroQoL-5-Dimensions-5-Level (EQ-5D-5L) questionnaire [7], there are currently no algorithms to assign this utility to the SF-36 questionnaire. Therefore, we used an algorithm developed for the United Kingdom [14].

By comparing the health utility calculated at baseline and after 9 weeks, we can estimate the change in the utility, which is then related to life expectancy, to calculate the therapeutic benefit in QALYs. The analysis assumed that the effect obtained during telerehabilitation lasts until the end of the patient's life. This does not mean that a constant QoL is assumed from telerehabilitation to the end of life, but that the difference in life utility between patients using telerehabilitation and those receiving standard care remains unchanged over the lifespan. Meanwhile, based on the TELEREH-HF trial, it was conservatively assumed that telerehabilitation does not translate into longer life

expectancy [5]. Finally, in the base case analysis, the further life expectancy adopted was 3.9 years. Considering the mean patient's age of 63 years, and the median reported life expectancy for those aged 65–69 years of 3.6 years, this assumption also seems to be conservative.

### Methods of assessing the costs

The costs of the initial (i.e., diagnosis and the first week of hospitalization) and the final assessment were not included, as these were identical for telerehabilitation and standard care. For telerehabilitation, the costs covered 8 weeks (i.e., 5 days/week, excluding weekends, when no telerehabilitation sessions were conducted), with a daily cost of 74 Polish zloty (PLN) (according to Regulation No. 133/2019/DSOZ issued by the President of the NHF). Thus, the total cost of telerehabilitation was estimated at 2960 PLN per patient.

In those undergoing standard care, most did not generate extra costs. However, rehabilitation was also used in 12% (51/425) of patients, 24% (12/51) of whom were rehabilitated in the hospital, and the rest (76% [39/51]) in an outpatient setting. Inpatient rehabilitation (7 days/week for 5 weeks) was estimated at 218.40 PLN/day (according to Regulation No. 133/2019/DSOZ issued by the President of the NHF), resulting in a cost of 7644 PLN per patient. Outpatient rehabilitation (24 days) was estimated as 74 PLN/day (according to Regulation No. 133/2019/DSOZ issued by the President of the NHF), resulting in a cost of 1776 PLN per patient. Finally, the mean cost of standard care was calculated as:  $12\% \times (12/51 \times 7644 + 39/51 \times 1776) = 378.80$  PLN.

Therefore, the cost difference between telerehabilitation and standard care is 2581.20 PLN. The costs are incurred in the first weeks after enrolment and are not discounted.

## RESULTS

### Base case analysis

Using the NYHA class shift approach, we obtained an average utility difference of 0.01187 between telerehabilitation and standard care. For the SF-36-based approach, the average change in utility in the telerehabilitation group during the ninth week was 0.01 (95% confidence interval [CI], 0.0016 to 0.0184) compared to 0.0028 (95% CI, -0.0056 to 0.0112) in the standard care group. This difference in the mean effect (i.e., 0.00726) was taken as the annual measure of telerehabilitation benefits. The cumulative effect difference over 3.9 years, at the discount rate of 3.5% per year, gives a total of:

- $3.71 \times 0.01187 = 0.044$  QALY for the NYHA-based approach, and
- $3.71 \times 0.00726 = 0.0269$  QALY for the SF-36-based approach.

The difference in the costs is 2581.20 PLN. Therefore, the ratio of the additional cost to the additional effect expressed in QALY, i.e., incremental cost-utility ratio (ICUR), is:

- $2581.20/0.044 = 58\,663.42$  PLN/QALY for the NYHA-based approach, and
- $2581.20/0.0269 = 95\,955.39$  PLN/QALY for the SF-36-based approach.

Incremental cost-utility ratio is interpreted as an average cost of getting an additional unit of the therapeutic effect when using the analyzed technology in place of the comparator. In Poland, the threshold differentiating cost-effective technologies from cost-ineffective technologies has been adopted by law and equals three times the annual gross domestic product per person, i.e., currently 155 514 PLN/QALY [15]. Therefore, in both approaches of calculating the effect in the form of utility, we found that telerehabilitation is cost-effective, i.e., the additional costs are justified by the outcomes gained.

### Sensitivity analysis

#### Influence of lifespan and effect persistence

In the base case, a further life expectancy equal to 3.9 years, and the persistence of the effect difference between groups of patients throughout life was adopted. Supplementary material, Table 3 presents the impact of these assumptions on the results. Various variants concerning the number of years of the effect's persistence have been presented (the life expectancy itself is irrelevant in the model, but it exceeds the duration of the effect). The effects obtained during these years were discounted the same way as in the base case.

The longer the duration of the effect, the lower the ICUR value, which proves the higher cost-effectiveness of telerehabilitation. Importantly, when parameterizing the effect based on the NYHA, even when the effect endures for 2 years, it can already be concluded that it is cost-effective. With the SF-36 approach, a 3-year duration of the effect is needed.

Considering both approaches collectively, a 2-year period of the telerehabilitation effect is sufficient for cost-effectiveness.

#### Lack of discounting

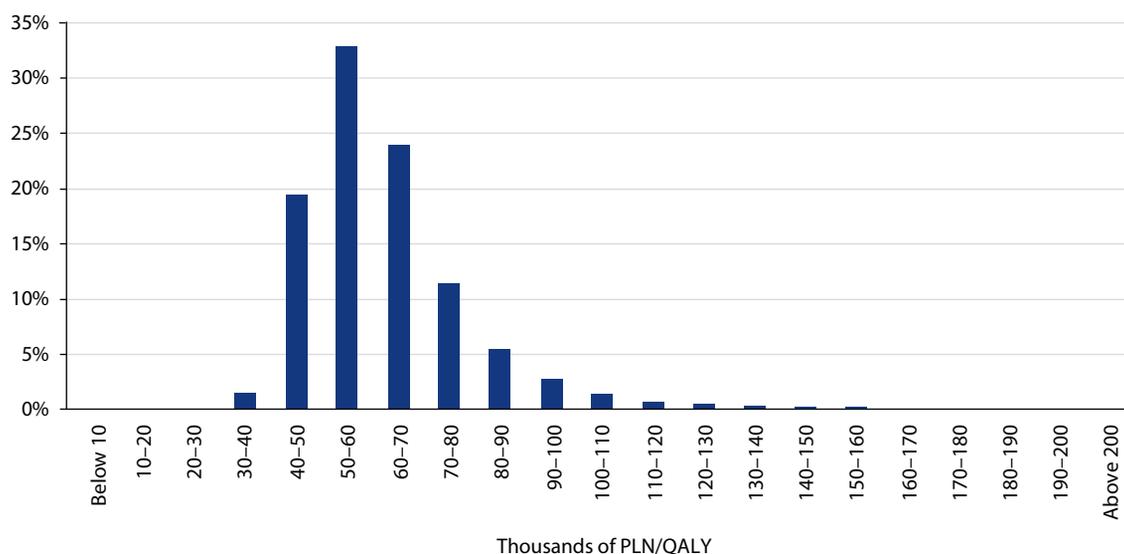
No discounting in the base case resulted in:

- $3.9 \times 0.01187 = 0.0463$  QALY for the NYHA-based approach, and

**Table 3.** The impact of New York Heart Association (NYHA) classes and 36-item short form questionnaire (SF-36) effects duration

The number of years the benefit of the utility persists	ICUR (based on NYHA class) [PLN/QALY]	ICUR (based on SF-36) [PLN/QALY]
1	217 456	355 537
2	110 598	180 826
3	74 993	122 612
4	57 201	93 522
5	46 534	76 082

Abbreviations: ICUR, incremental cost-utility ratio, QALY, quality-adjusted life year, PLN, Polish zloty



**Figure 1.** Distribution of the incremental cost-utility ratio (in thousands of Polish zloty per quality-adjusted life year [PLN/QALY]) for the New York Heart Association class-based approach considering the uncertainty of the New York Heart Association class distribution after telerehabilitation

- $3.9 \times 0.00726 = 0.0283$  QALY for the SF-36-based approach. In this case, the ICURs are:
- $2581.20/0.0463 = 55\ 757.89$  PLN/QALY for the NYHA-based approach, and
- $2581.20/0.0269 = 91\ 63.38$  PLN/QALY for the SF-36-based approach.

### Probabilistic analysis

To determine the effect of stochastic uncertainty in the data on the results obtained, a probabilistic sensitivity analysis was performed using the Monte Carlo method. In terms of the NYHA-based approach, the impact of the target structure uncertainty of the NYHA classes was investigated. Ten thousand bootstrap samples were generated, and their ICUR values calculated, resulting from the observation of the population structure appropriate for a given sample after 9 weeks. As shown in Figure 1, for almost all Monte Carlo iterations, the ICUR value is below the applicable profitability threshold, which indicates a very high resistance of the obtained conclusions to the uncertainty associated with the use of random tryouts. Importantly, studies on the relationship between the NYHA class and utility cover a very large number of patients and are characterized by high convergence of the presented results. Therefore, this element of the model is not an important source of additional uncertainty.

Regarding the SF-36-based approach, the effect of uncertainty related to the value of the utility difference was examined for both subgroups of the TELEREH-HF study. The parametric bootstrap method was used. The mean and standard deviation of change in utility between baseline and week 9 were calculated for each group, yielding 0.00276 and 0.0846 for the control group, and 0.01 and 0.08375 for the telerehabilitation group. Based

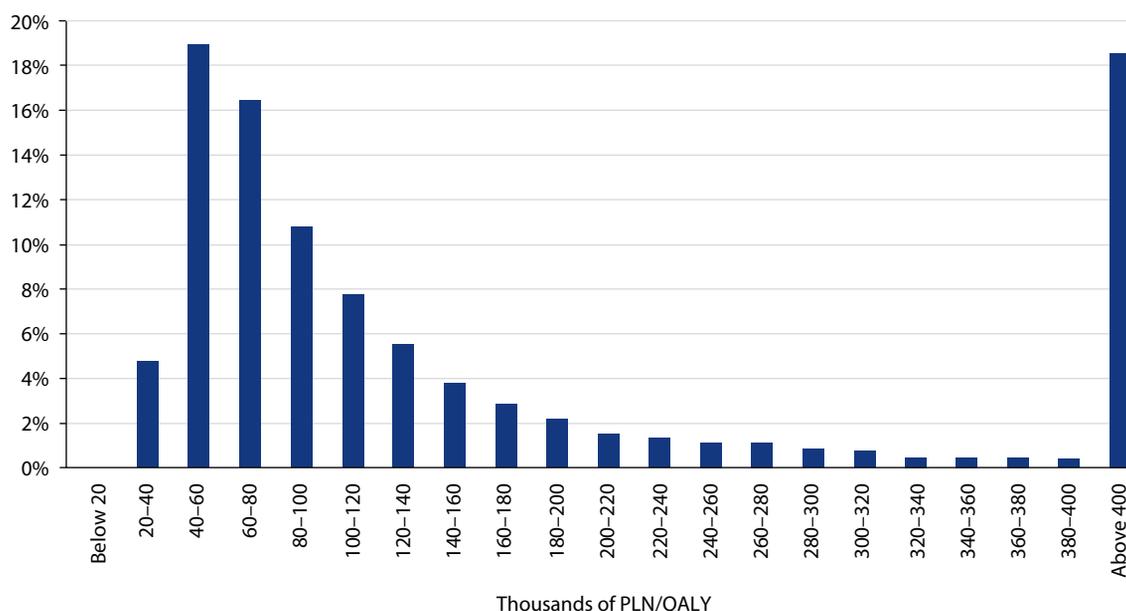
on the size of both groups (393 and 385 patients, respectively), a normal distribution was assumed to estimate the uncertainty of the mean: the standard error of the mean was approximately 0.0043 in both groups. The Monte Carlo simulation generated 10 000 utility difference values from this distribution. As shown in Figure 2, the uncertainty of the estimates using this approach is much greater; still, for approximately 68%, the ICUR value does not reach the profitability threshold in Poland, indicating the cost-effectiveness of telerehabilitation.

### DISCUSSION

This study analyzed the economic viability of telerehabilitation in heart failure. When estimating health-related utility gain, two approaches were used: one based on the improvement in the NYHA class, and another based on QoL measured with SF-36. For both approaches, telerehabilitation was found cost-effective, i.e., the cost of one QALY gained is below the statutory threshold in Poland.

The specific results obtained for both approaches are different: such differences are expected in the case of instruments based on the subjective assessment of QoL. Additionally, for the NYHA and SF-36, different algorithms were used to convert their values into utility, as they are different instruments. Nonetheless, despite the quantitative differences, both approaches gave consistent findings.

Unfortunately, in the case of both the NYHA and SF-36, no Polish data was available that could be converted into utility values to specifically reflect societal preferences in Poland. In this context, it is important that the difference between the obtained ICUR coefficients and the statutory threshold is large and gives a large margin of freedom for the model parameters. For example, if we take 2.5 years instead of the assumed effect duration of 3.9 years, telerehabilitation remains a cost-effective option.



**Figure 2.** Distribution of the incremental cost-utility ratio (in thousands of Polish zloty per quality-adjusted life year [PLN/QALY]) for the 36-item short form questionnaire approach including the uncertainty in the distribution of the utility change in both groups

The greater uncertainty of the estimates based on the SF-36 is interesting. Perhaps this is due to the greater number of aspects covered by this instrument, leading to greater 'noise' in a given sample. Another reason may be that in the probabilistic analysis based on SF-36, uncertainty was considered for both the telerehabilitation and control groups, both in terms of the initial and target utility levels. For the NYHA-based approach, only the structure of the telerehabilitation group was considered uncertain, and only after 9 weeks of care. In conclusion, the results of both the base case analysis and the sensitivity analysis indicate the cost-effectiveness of telerehabilitation.

The compared groups were not homogeneous. In the telerehabilitation group, some patients did not follow the doctor's instructions. In the group of patients who did, the results expressed by SF-36 were slightly better (utility increases by 0.0107 vs 0.01), indicating a slightly larger difference in the change in utility between the telerehabilitation and standard care groups (by approx. 10%). Additionally, different results were reported for the participating centers, which could be interpreted in a future post-hoc analysis with corresponding limitations. Moreover, some patients in the control group received rehabilitation, and likely achieved better results; thus, the comparison is conservative for telerehabilitation. It should be noted the analysis also covered the costs of extra rehabilitation in the control group, so the overall impact on ICUR should not be significant.

The analysis assumed a constant difference in utility gain related to telerehabilitation over standard care, which might be perceived as a less conservative approach. To explore that assumption, we estimated the necessary duration of effects, both in the NYHA and SF-36, to maintain

the cost-effectiveness of telerehabilitation. The estimated 2-year duration of the effects represents roughly half of anticipated mean survival.

Telerehabilitation has been shown to be cost-effective in Belgium [16]. In the randomized study of total 126 patients, a 6-month telerehabilitation resulted in QoL improvement, which translated into incremental QALY gain of 0.22. This stronger effect may be due to longer duration of telerehabilitation itself, longer follow-up period, greater sensitivity of the EQ-5D instrument, or the sensitivity of the utility attribution algorithm to various health conditions to telerehabilitation outcomes. Lower costs were additionally observed in the telerehabilitation group, mainly due to lower costs of rehospitalization. In the TELEREH-HF study, no such differences were observed.

Lower costs in the telerehabilitation group were also observed in an Australian study [17], although no improvement in the QoL was found, which may reflect its significantly shorter follow-up than in the Belgium study [16]. Telerehabilitation was reported cost-effective due to the savings generated. Similar results were reported for New Zealand [18].

In Denmark, an analysis of the effectiveness of telerehabilitation compared to traditional rehabilitation also showed that the additional costs generated were small (approx. 1700 EUR) [19]. However, the differences in QALY over the one-year horizon, although in favor of telerehabilitation, were not significant. This study used the SF-36 to measure QoL, which may suggest a low sensitivity of this instrument in the context of the considered intervention.

The economic modeling reported savings generated by telecare and an additional effect of approximately 0.03 QALY per year, although authors stressed that the

financial benefits may not apply to patients with low baseline risk [20].

The benefits of telerehabilitation not included in the present study should also be noted. Better health outcomes can lead to lower patient resource use and costs. Telerehabilitation may improve access to healthcare, as care can be provided regardless of whether a patient lives close to the rehabilitation center. Thus, telerehabilitation may increase the equity between patients. Telerehabilitation may also increase the possibilities of using the existing base by releasing resources in outpatient clinics and hospitals, which may motivate service providers to promote telerehabilitation care.

## CONCLUSIONS

The telerehabilitation compared to standard care was found to be cost-effective, i.e., additional costs are justified by the clinical effects gained. The additional cost of gaining one year of healthy life is in the range of 58 000–96 000 PLN/QALY, depending on the adopted approach, clearly below the profitability threshold in Poland. The therapeutic benefits are driven by the improvement of the patients' clinical condition, the NYHA class, or their QoL as measured by the SF-36 questionnaire.

## Article information

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