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Cost-Utility Analysis and Value-based Pricing of Digital Therapeutics for Pulmonary Rehabilitation in Patients with Chronic Respiratory Disease

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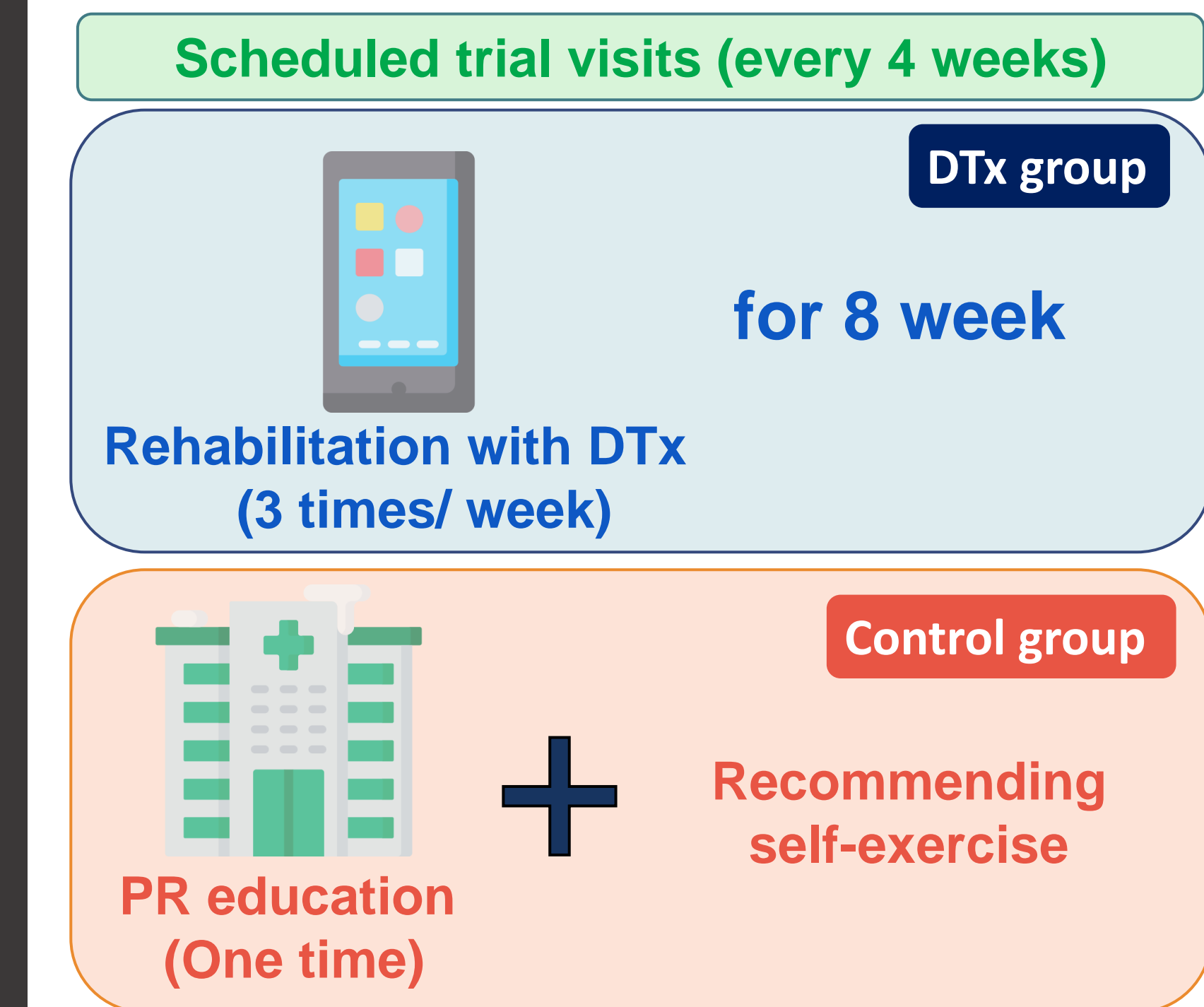
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Background

- **Chronic respiratory diseases (CRD)** such as COPD and interstitial lung disease are globally prevalent noncommunicable conditions.
- **Pulmonary rehabilitation (PR)** improves physical function and quality of life in patients with CRD.
- **Digital therapeutics (DTx) for PR**, the EASYBREATH app demonstrated significant improvement compared to the standard treatment in 8-week randomized controlled trial (RCT)¹.
- **Objectives:** To evaluate the cost-effectiveness of a DTx for PR and to explore a corresponding value-based price.

Methods

Overview of RCT



Trial based cost-utility analysis

Cost

- **Data source:** Electronic medical records (EMR) from the trial institution
- **Cost items:** Medical cost, pharmaceutical costs, DTx fee (only DTx group)
- **Perspective:** Korean healthcare system

Utility

- **CAT to EQ-5D-3L mapping:** Korean mapping algorithm (Lim et al., 2019)²

Analysis

- **Outcome:** Incremental cost-utility ratio (ICUR)
- **Willingness-to-pay (WTP) threshold:** \$19,410 per QALY, the Korean GDP per capita in 2006

Sensitivity analysis

- **One-way deterministic sensitivity analysis (DSA)**
- **Probabilistic sensitivity analysis (PSA)**

Value-based pricing (VBP)

- VBP was defined the maximum 8-week DTx usage costs maintaining cost-effectiveness.
- The DTx cost was reverse-calculated by setting the ICUR equal to the WTP threshold.

Results

Baseline characteristics

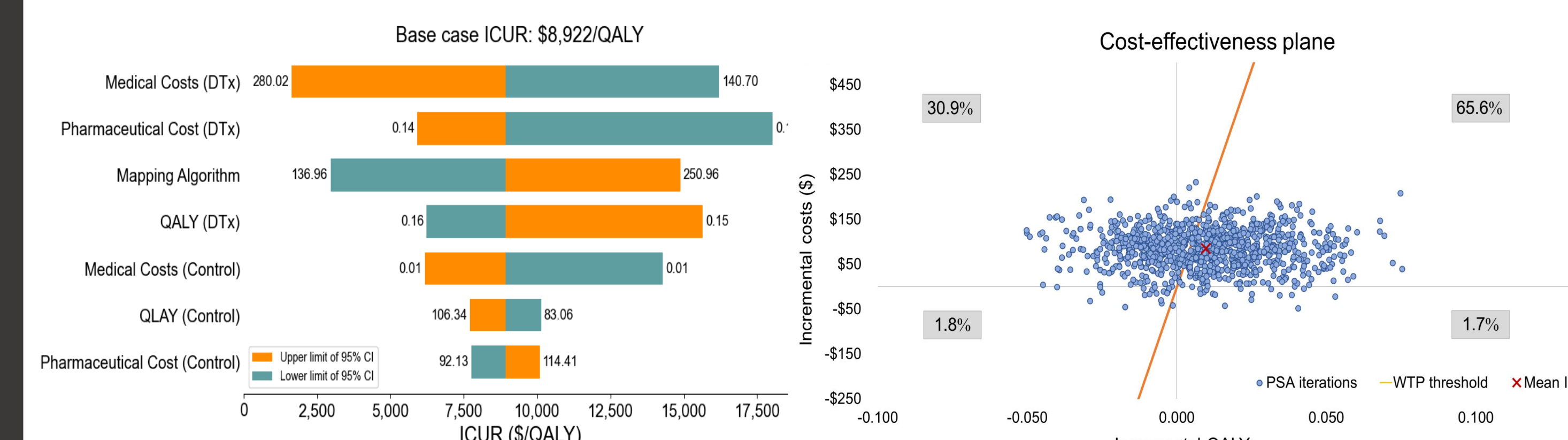
- Among 84 participants, 43 participants were allocated in DTx group.
- The baseline characteristics of the patients were comparable, except for age.

| Characteristics | DTx group (N = 43) | Control group (N = 41) | P-value |
|------------------------------|-----------------------|---------------------------|---------|
| Age, mean (SD) | 63.40 (10.36) | 67.78 (6.93) | 0.026 |
| Male gender, n (%) | 34 (79.07%) | 36(87.80%) | 0.435 |
| Clinical efficacy, mean (SD) | | | |
| 6MWD (in meter) | 495.67 (64.15) | 474.54 (73.36) | 0.163 |
| mMRC | 1.30 (0.71) | 1.29 (0.68) | 0.949 |
| CAT total score | 17.67 (6.03) | 17.63 (7.39) | 0.978 |
| SGRQ-total | 30.06 (12.90) | 28.45 (13.99) | 0.584 |
| HADS-total | 9.12 (5.62) | 9.98 (5.83) | 0.494 |

Abb. COPD, Chronic obstructive pulmonary disease; mMRC, modified Medical research council dyspnea scale, CAT, COPD assessment test; SGRQ, St. George's respiratory questionnaire; HADS, Hospital anxiety and depression scale.

Sensitivity analysis

- In the DSA results, medical and pharmaceutical costs of DTx were the most influential cost items affecting the ICUR.
- In 1,000 simulations, 65.6% of ICURs were in the northeastern quadrant, with a 60.2% probability of cost-effectiveness for DTx at the WTP threshold (\$19,410/QALY).



Acknowledgment

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2. Lim J, Choi SE, Bae E, Kang D, Lim EA, Shin GS. Mapping analysis to estimate EQ-5D utility values using the COPD assessment test in Korea. *Health Qual Life Outcomes*; 2019 (17):97. PMID:31170982. doi: 10.1186/s12955-019-1148-3.

Cost-utility analysis

| | DTx group (N=43) | Control group (N=41) | Difference ^a |
|-----------------------|---------------------|-------------------------|-------------------------|
| Total Costs (\$) | 390.4 | 305.1 | 85.33 |
| Medical costs | 196.44 | 94.70 | 101.74 |
| pharmaceutical costs | 194.96 | 210.36 | -15.4 |
| Total QALY (0-8 week) | 0.157 | 0.147 | 0.0096 |
| QALY (0-4 week) | 0.0822 (0.010) | 0.0795 (0.011) | 0.0027 |
| QALY (0-8 week) | 0.0746 (0.016) | 0.0678 (0.013) | 0.0068 |
| ICUR (\$/QALY) | | 8,922 | |

Abb. DTx, Digital therapeutics; QALY, Quality adjusted life year; ICUR, Incremental cost-utility analysis.

^aDifference was calculated by subtracting control group value from digital therapeutics (DTx) group value.

- DTx was **cost-effective** compared to standard treatment, with an **ICUR of \$8,922**.
- The VBP, representing the maximum cost-effective price for DTx usage, was **\$192**.

Discussion

Summary

- This trial-based cost-utility analysis demonstrated that DTx improved health-related quality of life. The ICUR was \$8,922 per QALY, which was within the cost-effectiveness threshold.

Limitations

- The analysis was limited by a short-term time horizon and a small sample size.
- The societal perspective could not be considered due to the lack of productivity loss data for DTx users with CRD.

Study implications

- This study applied QALY-based pricing analysis to innovative medical technologies, specifically evaluating the cost-effectiveness and value-based pricing of a DTx.
- To the best of our knowledge, this is the first study to evaluate both the cost-effectiveness and value-based pricing of DTx for pulmonary rehabilitation.

Conclusions

- Our findings indicate that DTx-based pulmonary rehabilitation could serve as an effective treatment option for managing CRD patients and provide valuable evidence for healthcare decision-makers.
- However, further research is needed to explore the long-term effectiveness and indirect costs.