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OBJECTIVE

- To assess whether clinical trials for non-pharmaceutical interventions are collecting quality of life and cost data
- This area of product evaluation is becoming more pertinent as regulations for medical technologies progress toward those for pharmaceuticals.
- This case study is performed in the US heart failure population.

METHODS

- A systematic literature review (Prospero registration CRD42023410084) was conducted in PubMed and EMBASE to identify literature published between 2008 and 2023.

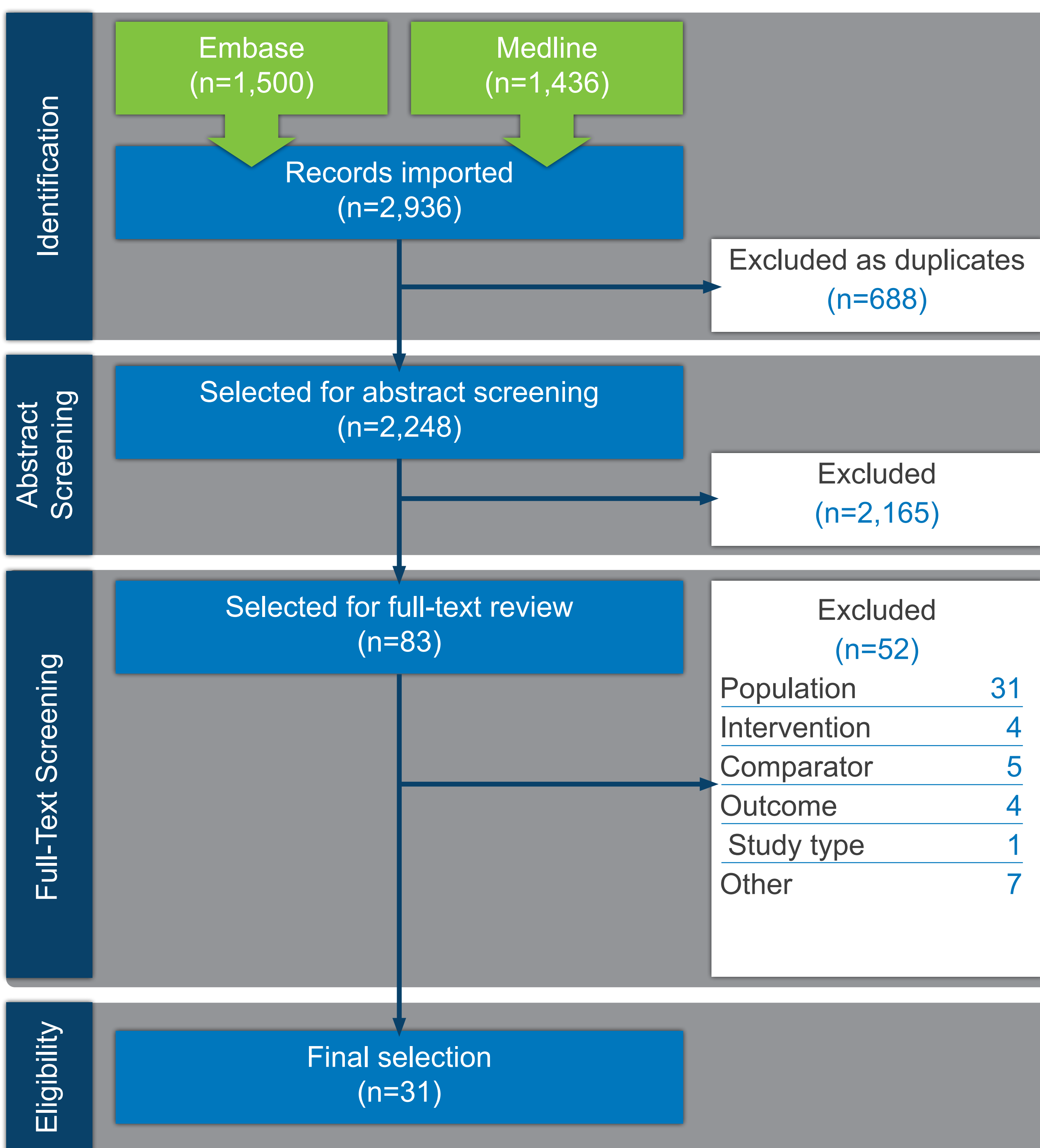


Figure 1 PRISMA diagram of the systematic literature review

- The inclusion criteria were randomised clinical trials with patients in the US over the age of 18 who fulfilled all following criteria:

- Diagnosed with heart failure in the last 12 months
- Intervention of heart failure monitoring
- Comparator of watchful waiting

RESULTS

- Searches identified 2,248 unique abstracts across the two databases.
- After title and abstract screening and full-text review, 31 studies were included for analysis. (Figure 1)
- Two of 31 studies (6.5%) reported on both quality of life and costs. (Figure 2)
- Ten studies (32.2%) reported on quality of life, with the Minnesota Living with Heart Failure and the Kansas City Cardiomyopathy Questionnaire being used equally. (Table 1)
- Four studies (12.9%) reported on costs, with the most commonly collected being total cost of care, which ranged from USD 11,000 to USD 52,000 (2022 USD) per patient.
- Heterogeneity in the type of costs collected was evident.

Table 1 Quality of life and/or cost reporting in the included studies

Publication	Quality of life measure	Costs reported
Abraham 2011 ¹	MLHFQ	No
Bekelman 2015 ²	KCCQ	No
Blum 2014 ³	MLHFQ & SF-26	Yes
Dorsch 2021 ⁴	MLHFQ & SCHFI	No
Jayaram 2017 ⁵	KCCQ	No
Johnson 2022 ⁶	KCCQ	No
Lindenfeld 2021 ⁷	KCCQ & EQ-5D	No
Madigan 2013 ⁸	KCCQ	No
Ong 2016 ⁹	MLHFQ	No
Schwarz 2008 ¹⁰	MLHFQ	Yes
Soran 2008 ¹¹	-	Yes
Tompkins 2010 ¹²	-	Yes

MLHFQ: Minnesota living with heart failure questionnaire, KCCQ: Kansas City Cardiomyopathy Questionnaire, SF-36: 36-item short form survey, SCHFI: Self-care heart failure index; EQ-5D: EuroQol 5-dimension quality of life questionnaire

CONCLUSION

- In heart-failure clinical trials of non-pharmaceutical interventions, costs and quality of life are infrequently reported
- There is room for improvement in this area of clinical trial design for medical technologies.
- At this time, health-economic analysis of single trials for medical technology will remain rare in the heart-failure population.

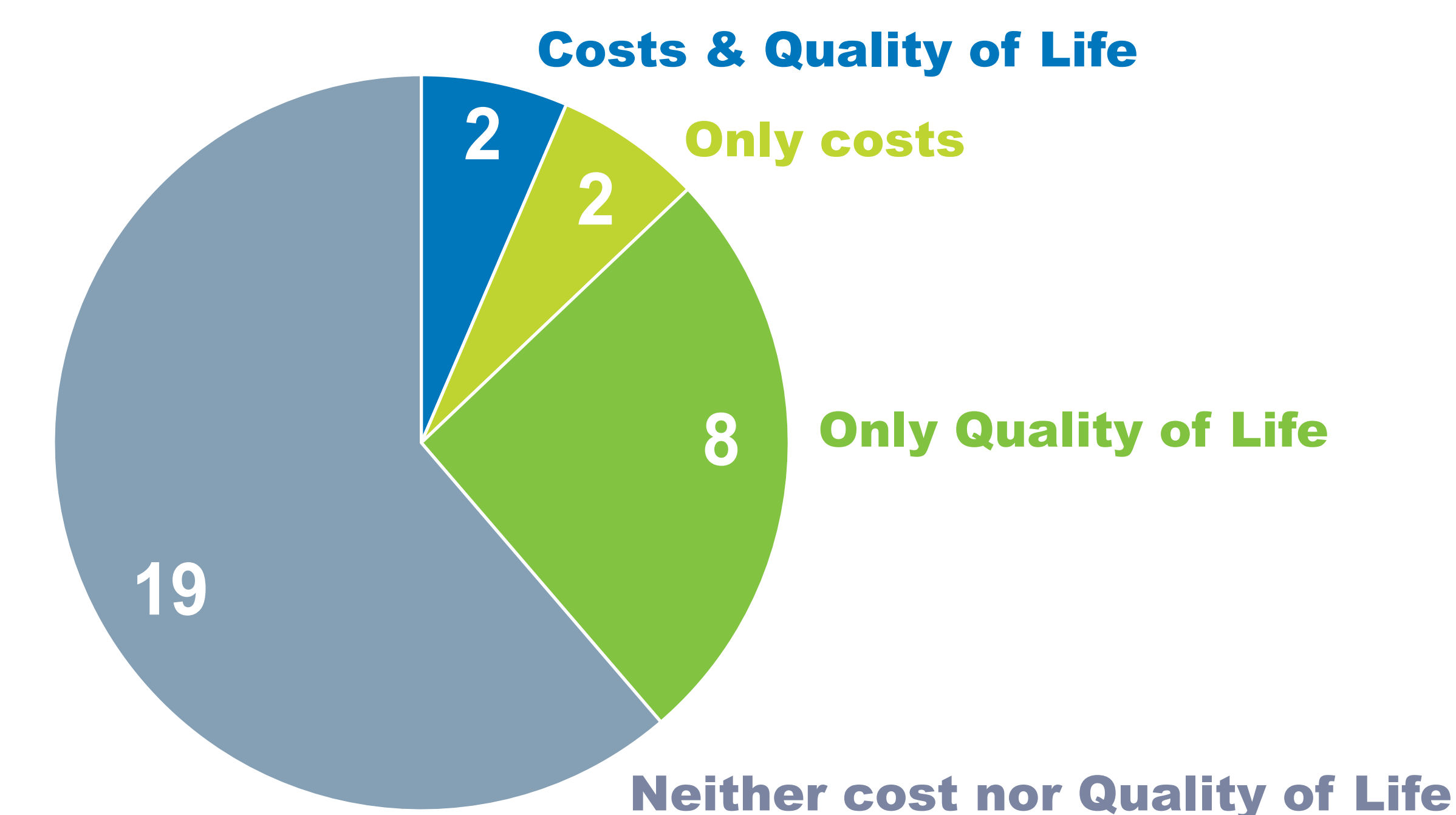


Figure 2 Investigated studies including costs, quality of life, or both

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Disclosure

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