

# **Mesenchymal Stromal Cell-Derived Exosomes and Extracellular Vesicles Across Therapeutic Indications: A Structured Review of Published Preclinical and Early-Phase Clinical Study Designs, Administration Parameters, and Reported Outcomes**

Andrew Jonathan Hillman

ORCID 0009-0001-5396-321X

DOI: 10.5281/zenodo.21209814 (all versions). This version: 10.5281/zenodo.21209815.

<https://andrew-hillman.com/publications/msc-exosomes-evs-structured-review/>

Published 2026-07-05. License: CC BY 4.0.

This PDF reproduces the summary page for this paper at <https://andrew-hillman.com/publications/msc-exosomes-evs-structured-review/>. The full paper is at <https://doi.org/10.5281/zenodo.21209814>.

## **Summary**

This structured review summarizes published preclinical and early-phase clinical studies of mesenchymal stromal cell exosomes and extracellular vesicles across therapeutic indications. It records study designs, administration parameters and reported outcomes, and attributes every result to the original authors. FDA has not approved any exosome or MSC-EV product, and human use requires an IND or BLA.

Exosome and mesenchymal stem cell-derived extracellular vesicle products are not approved by the FDA for any indication. This paper describes published scientific literature. It does not describe an available treatment.

## **Questions this paper covers**

- What do recent reviews say about MSC exosomes and extracellular vesicles?
- What are MSC exosomes?
- Are any exosome products FDA approved?
- How do published studies report exosome dosing and administration?
- Why do reviews of MSC-EV studies urge caution?

## **Sources**

1. Witwer KW et al. Defining mesenchymal stromal cell (MSC)-derived small extracellular vesicles for therapeutic applications. J Extracell Vesicles. 2019. PMID 31069028
2. Welsh JA et al. Minimal information for studies of extracellular vesicles (MISEV2023). J Extracell Vesicles. 2024. PMID 38326288

3. Mizenko RR et al. A critical systematic review of extracellular vesicle clinical trials. J Extracell Vesicles. 2024. PMID 39330928
4. Lener T et al. Applying extracellular vesicles based therapeutics in clinical trials, an ISEV position paper. J Extracell Vesicles. 2015. PMID 26725829
5. FDA Public Safety Notification on Exosome Products, Dec 6, 2019

Educational content. It is not legal or medical advice.