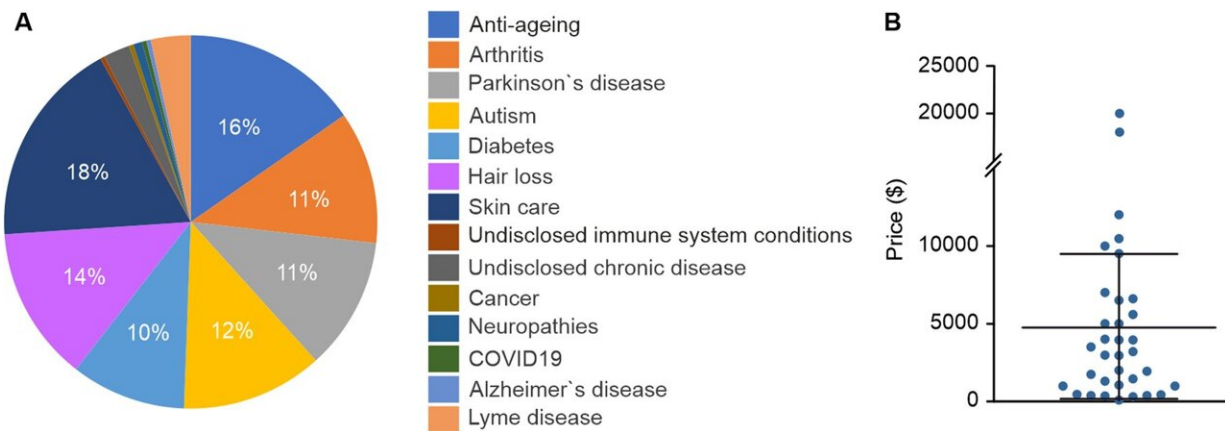


# Scientists call for regulation of stem cell 'treatment' fads

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Indications and pricing for stem cell secretome-based interventions offered by the direct-to-consumer businesses. A Types of cosmetic or medical conditions treated by the direct-to-consumer businesses. B Pricing of the marketed interventions. Credit: *Stem Cell Research & Therapy* (2023). DOI: 10.1186/s13287-023-03335-2

Scientists are calling for tighter regulation of stem cell treatments, after finding hundreds of clinics worldwide offering unproven "therapies" for conditions as varied as hair loss and Parkinson's.

Researchers at the University of Reading and the Universiti Sains Malaysia have identified 114 companies in over 20 countries offering unproven, unregulated, stem-cell derived products to consumers. They

are calling on regulators to halt these products until they can be proven safe and effective in clinical trials.

The findings have been published in the journal *Stem Cell Research & Therapy*.

Dr. Darius Widera, an Associate Professor at the University of Reading and lead author of the research, said, "Companies that sell untested and unproven health promises are little more than modern snake-oil salesmen. The vast majority of the stem cell treatments offered are not yet, and may never be, backed by research that supports therapeutic use.

"This may put potentially vulnerable and sometimes desperate people at risk of losing large amounts of cash for treatments that don't work or are even dangerous. Regulators must act now to protect people."

## **No completed trials**

One of the latest fads in stem cell therapeutics is the use of secretomes, extracellular vesicles, and exosomes, derived from stem cells. Rather than using whole stem cells, clinics are using the products that are produced by those cells.

There is some evidence that these products have a similar potential to support regenerative medicine as adult stem cells. Currently, 433 [clinical trials](#) have been registered on the ClinicalTrials.gov database, the researchers found. Very few have been completed, and these products are thus far poorly regulated. They are only being offered in [private clinics](#). No state health provider has yet approved their use.

The U.S., Mexico, United Arab Emirates, and Malaysia, combined, have more than half of the clinics worldwide, the researchers found. The scientists found four clinics in the U.K. offering treatments based on

stem cell products at the time of conducting their research. However, they say more have since appeared in the U.K., and are potentially advertising similar services.

The researchers found that 63 of the companies offered interventions of secretomes from stem cells derived from one of a number of sources, not related to the consumer. Thirty companies had treatments using secretomes from the client's own cells. Twenty-one companies didn't disclose what type of cells their treatments are derived from.

Most of the companies didn't disclose the particular tissue the cells were found in, the study finds. Of those that did, the most common source was blood, followed by [amniotic fluid](#), fat tissue, bone marrow, and umbilical cord.

## **Skin care to autism**

Skin care, anti-aging, and [hair loss](#) were the most common targets for intervention, but significant numbers of clinics were also claiming to treat autism, arthritis, Parkinson's disease, diabetes, or Lyme disease. Some did not disclose which "[chronic diseases](#)" they claim to treat. A handful mentioned neuropathies, rare immune system conditions, COVID-19, or Alzheimer's.

Dr. Widera said, "At best, consumers are gambling their money, in amounts from \$99 to \$20,000, on treatments for which there is no reliable evidence. At worst, these treatments could be harmful.

"Any [medical procedure](#) carries a risk. People can develop [allergic reactions](#) and infections, and there are sometimes very [serious side effects](#) from having an unproven product introduced to your body."

Dr. Graeme Cottrell, a co-author of the study at the University of

Reading said, "There is also huge potential for exploitation. People who live with chronic or degenerative conditions, and their loved ones, desperately want to find something that will offer some relief from symptoms. They are often woefully under-served by the available therapies and treatments and are willing to try pretty much anything that sounds like it might work.

"As scientists, we can offer our evidence-based opinion on the treatments being offered, but we don't have the power that regulators do. It is vital that regulators in all the affected countries catch up swiftly."

**More information:** Atiyeh Asadpour et al, Uncovering the gray zone: mapping the global landscape of direct-to-consumer businesses offering interventions based on secretomes, extracellular vesicles, and exosomes, *Stem Cell Research & Therapy* (2023). [DOI: 10.1186/s13287-023-03335-2](https://doi.org/10.1186/s13287-023-03335-2)

Provided by University of Reading

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