

# Considerations for Stem Cell Interventions



You may wonder if stem cell therapy could heal, ease, or cure your arthritis or joint pain. Promising research is being conducted in an ethical and appropriate way, but there are doctors and others performing unproven stem cell interventions and experiments on patients, bypassing regulatory laws and ethical standards of medical care and research.

The Arthritis Foundation is concerned that stem cell interventions are being sold and marketed directly to patients prior to proof of safety and efficacy. We recommend caution, for the sake of your health.

It's important to know that no stem cell interventions are currently approved by the FDA for any type of arthritis or joint injury, although you may see advertisements for them and read about celebrities getting these interventions.

Below are some facts you should know and some good reasons to be cautious when considering unproven stem cell interventions, which we do not refer to as treatments or therapies because they are not proven.

## What Should I Consider? Why This Is a Concern

<p><b>Advertising and promotions marketed directly to you</b></p>	<p>Doctors whose specialty is treating arthritis receive patient referrals from other health care providers, while centers selling unproven stem cell procedures instead market directly to patients through persuasive language on billboards, social media, the internet, newspaper advertisements, TV, etc.</p>
<p><b>Being required to provide personal information to "learn more"</b></p>	<p>For-profit stem cell centers spend money on advertising and promotions rather than on research to learn what is safe and effective for patients.</p>
<p><b>False and misleading advertising that the stem cell intervention:</b></p> <p>A. Is FDA-approved</p> <p>B. Does not require FDA approval</p> <p>C. Is a legitimate clinical trial because it is listed on <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a></p>	<p>a. Today, there is still no stem cell intervention that has been approved for any arthritis indication. Many centers are dishonestly referring to the device used for harvesting or spinning cells, which are not approved for arthritis indications. Some centers fraudulently advertise FDA-approved allograft stem cell therapy for arthritis, but this therapy is not approved for arthritis since it has not been proven safe or effective in a clinical trial for arthritis indications. This use is called "off-label," which often means insurance won't cover the procedure.</p> <p>b. When clinical trials are not conducted under an Investigational New Drug (IND) application, it means that the FDA has not reviewed the experimental product or procedure to help make sure it is reasonably safe.</p> <p>c. Congress passed a law requiring a resource listing clinical trials, but the trials listed on <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> have not been regulated by anyone. FDA recently released draft guidance to deter false information from being posted, yet we prefer arthritis patients use The Arthritis Trial Finder when they are searching for valid clinical trials: <a href="https://trials.arthritis.org">https://trials.arthritis.org</a>.</p>
<p><b>False and misleading claims the intervention is improving the disease based on athlete, celebrity and patient testimonials</b></p>	<p>Unless clinical research has been conducted and evaluated, it is very difficult to know if an improvement is due to a perceived or true effect of the treatment or due to many other factors, such as an intense belief that it will work, complementary treatments or supplements accompanying the treatment, healthy lifestyle changes made in combination with the treatment or natural fluctuations in your arthritis condition.</p>

<p><b>False and misleading claims that cells from your own body are automatically safe</b></p>	<p>Any time cells are removed from your body, there is a risk they may be contaminated with viruses, bacteria or other pathogens that could cause disease when reintroduced. Manipulation of cells by a clinic may interfere with their normal function, including those that control cell growth.</p>
<p><b>An experimental unproven stem cell intervention offered for sale is not the same as a clinical trial</b></p>	<p>The fact that a procedure is experimental does not automatically mean that it is part of a research study or clinical trial.</p>
<p><b>Multiple diseases treated with the same cells</b></p>	<p>Different types of stem cells come from different places in your body and have different functions. Without manipulation in a lab (not a clinic), tissue-specific stem cells can only generate the other cell types found in the tissues where they live. Thus, it is unlikely that a single cell type can be used to treat a multitude of unrelated diseases involving different tissues or organs.</p>
<p><b>Stem cell clinics doing only stem cell procedures</b></p>	<p>Doctors may be less tempted to push stem cell procedures to increase the bottom line if it is merely one component of a comprehensive practice which includes additional treatment options.</p>
<p><b>The source of the cells or how the treatment will be done is unclear</b></p>	<p>This should be clearly explained to you in a treatment consent form. In addition, there should be a 'protocol' that outlines the treatment in detail to the medical practitioner. The protocol is the 'operating manual' for the procedure. While it may not be made available to you automatically, you should be able to request this. Please also refer to the Patient Bill of Rights document.</p>
<p><b>High cost of treatment, repeat treatment costs and hidden costs</b></p>	<p>It is not customary for someone to pay to be in a clinical trial. You shouldn't pay for visits which are not standard of care with your care management team or experimental interventions.</p>
<p><b>Remaining a candidate for the procedure with a prior history of cancer</b></p>	<p>Anyone with a history of cancer should not consider procedures involving unproven stem cell interventions as they are marketed today because their manipulation of cells outside of a clinical trial with a qualified lab assessing function, safety and efficacy.</p>