

“I’ve Got Nothing to Lose by Trying It”

Weighing up claims about
cures and treatments
for long-term conditions

Introduction

Every month there are dozens of news reports about promising research, medical breakthroughs and wonder drugs. The internet is cluttered with adverts and chat-room conversations testifying to 'incredible' benefits.

For people with multiple sclerosis, Parkinson's disease, Alzheimer's, motor neurone disease or other long-term medical conditions such as rheumatoid arthritis, these stories offer more than interest. They offer the hope of finding something that will do more than their medicines can.

But the evidence for many treatment claims is unreliable. This leaves people unsure about what to try and uncertain where to draw the line. People often report that they get much needed comfort and relief from treatments outside the medical mainstream. Yet others worry that their hope for improvement is being exploited by promoters of dubious therapies based on pseudoscience. Some people with chronic conditions feel that they are put under pressure by well-meaning friends and relatives to try out advertised treatments, dietary regimes and exercises.

Even when the science is good, the route to progress is frustrating. A lot of research that looks promising in the early stages comes to a dead end. "Breakthroughs" in the lab that are successful take investment and many years of research to be translated into therapies that people can use. Clinical trials may reveal that a promising drug carries an unacceptable risk of side-effects. Often this process is not well communicated to the public.

How can you make sense of 'cure' stories; tell the beneficial from the bogus; the likely from the doubtful? Sense About Science and medical research charities have worked with patients, doctors and scientists to write this leaflet about medical claims for people with long-term neurological conditions. Most of the subjects covered here will also be familiar to people coping with other long-term health problems.

The material is drawn from information that patients say they have found useful, from common enquiries we've received and from answers from doctors and scientists to our questions about new therapies. We hope that it helps you find out more about how to evaluate claims about treatments in the news and on the internet.

Dr Aarathi Prasad
Sense About Science

Dr Laura Bell
Multiple Sclerosis Society

1. Medicine in the news: real hope or hype?

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Journalists take an interest in the development of treatments¹, but when you hear about new therapies it's often about research that is at too early a stage to know whether it will be medically useful. Headline writers may pay little attention to the detail of an article in their need for a catchy title, and can imply that cures are just around the corner. In short, results can be exaggerated.

2. I've got nothing to lose by trying it...nothing else works

page 6-7

The internet is full of adverts for treatments and cures. Untested treatments may be harmful and sometimes doing nothing might be better than 'giving them a go'. Furthermore, many treatments being marketed are not likely to do much at all, but cost time, energy, emotion and money that could be better spent elsewhere.

3. But why do unproven therapies seem to work?

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An unproven therapy *may* turn out to be effective; but we need scientific evidence before saying who it might help, what symptoms it might treat and what level of improvement, if any, it might bring. Adverts for such therapies often use recommendations and stories from individuals about the good results they experienced. Whether there's a commercial motive or not, personal stories about good results can't give a full picture of the effects of a treatment. Many things can make a personal story misleading and make a therapy sound more effective than it is: optimism, the 'placebo effect' or fluctuating symptoms, for example. And remember that a company promoting a therapy is unlikely to publish stories from people who did *not* have great results.

4. The role of clinical trials

page 9-11

Before any medicine can be used, clinical trials are needed to ensure that it is both safe and effective. All new medicines go through clinical trials to be assessed for whether they work better than the current treatment (if there is one) and placebo (dummy drug), and for side-effects. Clinical trials can specify the disease, disease stage, and the particular group in the population (e.g. adults rather than children) for which the medicine is being trialled. There are several phases of clinical trial, and it is after Phase III of the trial (see p.10) that it can be licensed by the government regulator, the Medicines and Healthcare products Regulatory Agency.

5. How do I know what to believe?

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There is no easy test of medical claims but it is possible to build up a clearer picture of research and evidence, and you should be alert to the ways that research is distorted. You can explore whether information about a treatment is reliable. (Have results been independently researched and then repeated? Has there been a clinical trial? Has it been published in a scientific journal? What is the treatment licensed for?)

- Delving deeper? (see p.13) gives you other sources of information available.
- Contacts (see p.14) gives you details of organisations interested in scientific research and treatments for long-term neurological conditions.

¹ Treatment refers to medicines, surgery and other medical therapies.

Cayce viewed the the usual cause of MS as a deficiency of GOLD in the body brought on by a failure of the digestive system to properly assimilate that mineral. To correct the gold deficiency, while avoiding the adverse effects often associated with administering that element, Cayce recommended a very mild, usually imperceptible mode of electrotherapy (vibratory medicine) which stimulates the body's uptake of gold from dietary sources

Nicotine offers new hope for Alzheimer's treatment

'Therapeutic cloning' could help treat Parkinson's disease

Nicotine no good for Alzheimer's

Medicine in the news: real hope or hype

News reports are of course looking for the new, so that is generally the emphasis used by people promoting research findings to reporters, and then by those reporters to convince their editors to give the story space. To set news stories in context a good port of call is the NHS Choices website (see *Delving deeper?* p.13), which provides the research background to news stories. Another source of information is the medical research charities, which fund research and monitor the overall picture. They produce bulletins on recent news and most have help-lines.

Here are some points to consider about what kind of research is being reported...

Good scientific research but too early to know whether it will work as a treatment

For example, some chemicals appear to alleviate problems in mice but haven't yet been tested in humans. When potential new drugs are tested in people they often don't have the same effect as in animals.

It might also turn out that the harm they do to people outweighs any benefit. The proportion of new agents that enter clinical trials and finally achieve a marketing license is approximately 1 in 10.

Look for references to the stage the research is at and whether a clinical trial is planned.

**Landmark
advance in
treatment
of brain
diseases**

**Stem cell
treatment
gives hope
on MS and
arthritis**

**Blood pressure drug
'cuts dementia risk'**

Coffee could halt multiple sclerosis
Stem cell breakthrough could

Promising early trial results but still much work to do

For example, great hope has been placed in the possibility of stem cell therapies. It's a dynamic area of research but, stem cell technology is still in its early stages and there are no licensed stem cell therapies available for neurological conditions. To find out what clinical trials are in progress visit the Current Controlled Trials website (see Delving deeper p.13).

Cautious research results inflated to create headline 'facts'

For example, studies that look for common lifestyle patterns in people who develop Alzheimer's² disease just tell us what was done or present at the time of the disease but they have led to news articles that claim adopting those lifestyles can prevent Alzheimer's, such as "The occasional curry 'could prevent Alzheimer's'"

Consider whether the headline (written by a sub-editor, not a specialised journalist) is backed up by what is said in the rest of the article. If you can get hold of the study report (see Delving deeper? p.13) you can find out what the researchers set out to do and what they actually conclude they have found.

Good media reports indicate whether the research has been published, and in which scientific or medical journal. Research published in scientific journals must pass the scrutiny of independent reviewers with experience in the field (peer review). They assess whether it is valid, significant and original work, how the study was designed and whether it supports the conclusions put forward by the researchers.

In all news reports about research, check for references to the study being published in a scientific journal. Be cautious of reported findings from scientific conferences; these often hit the headlines but the research findings may be preliminary and not yet published, and scientific scrutiny could show up weaknesses in the research or affect the conclusions.

Unfortunately, it is much harder to find out the background evidence for claims made on websites although medical research charities are a good place to check these out. *Be particularly wary of websites that use news reports to back up their scientific claims.*

² Daily Mail, 2 August 2006

Online, you needn't suffer alone

a great deal of his recovery down to taking Aqua Hydration Formulas

Clinic peddles false hope of cure

Omega 6 acid linked to risk of Alzheimer's

I've got nothing to lose by trying it... nothing else works

The internet can be a useful source of support and information for long-term conditions but you will also come across many interventions, such as diets and brain training regimes, promoted as treatments or cures. Some claim to tap into very new science; others to draw on tradition or ancient wisdom. Few are backed by scientific evidence to prove they work and they can cost a lot in money and disappointment. But many people with long-term diseases say they feel they should try anything to improve their symptoms.

Is something necessarily better than nothing...?

It is frustrating that sometimes drug treatments and medical therapies do not offer the benefits people need. Sometimes though, doing nothing may be better than trying an unproven therapy.

In the first place, some unproven treatments on offer could be harmful. There are clinics around the world that claim to offer stem cell therapies but which operate outside any form of regulation. They use the exciting headlines of press reports to suggest that their therapies are scientifically supported, but often their treatments (which can cost thousands of pounds) have not been safety-tested by UK standards. People going abroad for stem cell treatment are taking a huge risk. Often, they can't get trustworthy information about how the stem cells being used were obtained or whether they have been safety-screened for viruses, such as HIV or hepatitis. There is no responsibility for follow-up care. It's worth noting that the websites advertising this kind of treatment carry disclaimers, usually hidden away in small type, saying that they are not promising any clinical benefit.

The diet that can treat epilepsy

Drug for Parkinson's can slow progression of disease

a synergistic combination of ingredients that have been clinically demonstrated to improve memory and learning, improve mood, reduce anxiety, and increase ability to cope with stress.

Many unproven therapies on sale are unlikely to do much at all and neither treat nor harm. Whether or not treatments are dangerous, there is a cost in the time, energy, emotion and money that are spent on them.

"I tried so many changes to my eating and living habits that I ended up thinking I had bad days because of something I was getting wrong. I realised I'd picked up some weird ideas about what the disease actually was." **John**

Some of the web adverts for alternative products encourage the idea of a separate treatment regime from that prescribed by your GP. Testimonials talk about keeping alternative treatments secret. It's hard to see how this benefits patient care. Occasionally, alternative therapies have disastrously interfered with other treatments or people have stopped taking their prescribed medication which also causes harm.

"When I ask patients what they are taking for a condition they frequently don't report anything that they have been led to believe is 'natural'. Many of the most dangerous poisons are completely natural."

Dr Andrew Green, GP

Many people are aware that unproven, sometimes expensive therapies are being marketed in a way which appeals to their desperation for relief or hope. Some have been frustrated with the pressure they feel to try anything available.

Some good tips we've heard from people with chronic neurological conditions on finding a balance are:

- Approach it all with a wary eye, especially if you are parting with money.
- Be suspicious about websites that try to blind you with science-sounding information.
- Don't be pressurised into trying things, even when people around you mean well.
- If you have a neurological or other long-term condition, be particularly wary of treatments that claim to cure.

"We have heard about unscrupulous people making big profits from untested treatments. I feel strongly against this." **Carole**

"Allowing treatments to be made available which have not been through the established clinical trials process encourages unscrupulous individuals to market ineffective treatments for monetary gain." **Motor Neurone Disease Association**

and complimentary antiaging product called - Vitacel GH-8, from a friend and decided to order it as the price was affordable and the Vitacel 8 GH8 with Ginkgo Biloba was available in the USA. On three antiaging supplements a day, I noticed signs of improvement in his Alzheimer's disease symptoms.

a synergistic combination of ingredients that have been clinically demonstrated to improve memory and learning, improve mood, reduce anxiety, and increase ability to cope with stress.

The spasms disappeared only one month after the treatment. It was almost as if they had been blown away.

Can goats' blood help beat MS? My mother is walking proof it can
by Mrs Laurence Llewellyn-Bowen

On sale in the UK: unproven goats' blood treatment for MS patients

How a zap to the brain could offer hope for Alzheimer's sufferers

But why do unproven therapies seem to work?

Many people with long-term conditions find that sharing their experiences with others helps them and is a valuable source of support. But as a source of information about how effective a therapy might be, personal testimonies can give a misleading picture, for a number of reasons.

Just as people on diets look optimistically at the scales, people putting their money and energy into a therapy are inclined to look hopefully for any sign of improvement that could suggest it is working and worthwhile. This optimism can itself make some people feel better, since being down and fed-up can produce or exacerbate symptoms. Taking treatments, or having one-to-one sessions with a therapist, can also make people feel more in control and more positive.

When people take a 'dummy' treatment, which they believe might work, research has shown that about half of them will experience an improvement. This is a well known psychological response, which triggers a physical response, called the **placebo effect**. This response improves the effectiveness of regular medicines too.

Most long-term conditions have **fluctuating symptoms**, such as the pain associated with arthritis, which comes and goes on its own, and the symptoms of Parkinson's disease and multiple sclerosis. When symptoms are worse than usual, they are *more likely* to be followed by a period of returning to normal. People usually start to take a treatment when their symptoms are particularly bad and then, when they go back to normal, it appears that the treatment has worked.

You may also **improve or recover naturally** from some conditions. **This improvement may simply coincide** with a particular food, a specific event or using a treatment.

Some patients with neurological conditions have told us that they take unproven or unlikely therapies knowing that any effect they experience could well be for one of the above reasons, rather than because the therapy is altering their condition. They know that stories aren't reliable evidence. It is a very personal decision.

However, the evidence-based approach (in which a treatment is tested in rigorous clinical trials in large numbers of people) is the best way of finding out whether a treatment is having a real effect and whether it is safe.

'Wonder drug' may prevent onset of Alzheimer's

Stem cell injection trials raise hope of cure for MS

The public deserves protection from the false hope of 'wonder drugs'

Banished all the Frustrating Symptoms of this Cruel Condition from his Body... Naturally!

Understanding Clinical Trials

Before any medicine can be used, clinical trials are needed to ensure that it is both safe and effective. All new medicines go through clinical trials to be assessed for whether they work better than the current treatment (if there is one) and placebo (dummy drug), and for side-effects. The process can take years because of the various stages of testing including the collection and analysis of results (see the Phases of a Clinical Trial diagram below). **Although it takes time, if a medicine has gone through the first three phases of clinical trials, it means that you and your doctors will have access to information about the balance of benefits and harms.**

- ⇒ For some people the risk of harm from a new medicine or treatment can be greater than for others so it is a decision that needs to be taken in the context of your medical history and state of health.
- ⇒ Many unlicensed therapies and alternative remedies are not tested to such rigorous standards, if at all.

Remember that genuine, trustworthy trials will never expect you to make any payment. To find out whether there are relevant controlled trials for your condition you can consult www.controlled-trials.com. Specific trial websites provide more details including the ethical committee that approved it and how to discuss your suitability.

Understanding Clinical Trials

Phases of a Clinical Trial

There are three main phases of clinical trials before a medicine can be authorised for use.

After **Phase III** has been completed, an application can be made for the **medicine to be licensed** as a treatment for the **specific condition it was tested on**.

Phase I, What are the **side effects**? What **dosage** is safe to use? Test a small group of around **30 people (who do not necessarily have a condition)** to check.

Phase II, Does it work? **How safe** is it and **what dose** to give? Compare to a placebo and/or an existing treatment in up to **200 people with a specific condition**.

Phase III, also tests for **effectiveness** but in hundreds to thousands of people with the condition/ This means that more information on less common side effects can be collected.

And after a medicine receives permission to be sold, it is monitored and evaluated in the largest scale of the clinical trial, known as **Phase IV**.



Clinical trials can specify the disease, the disease stage, and the particular group in the population (e.g. adults rather than children) for which the therapy is being trialled. If these therapies are then prescribed for other groups of people or other conditions, we don't know what the risk/benefit calculations are and they could be very different.

For example, Naltrexone is licensed in the UK to help treat people who are addicted to opiates, such as heroin. However some people advocate its use in low doses (Low Dose Naltrexone - LDN) for the treatment of multiple sclerosis (MS).

Some people with MS have been prescribed LDN, but it is not currently licensed for MS in the UK because there is not enough evidence-based information at this time to prove that LDN is an effective treatment for MS. Doctors may be understandably cautious about prescribing medicines if the safety and effectiveness have not been proven.

You can find out whether a treatment is licensed for your condition from the Medicines and Healthcare products Regulatory Agency (see Contacts p.14).

Once a medicine has been licensed, doctors can prescribe it to people although some Primary Care Trusts might wait for the medicine to be approved by the National Institute of Clinical Excellence (NICE) before doing this. NICE is asked to assess particular medicines and devices when there is confusion or uncertainty over the value of a medicine or when prescribing practices vary across the country (patients may be receiving different prescribed treatments, depending on where they live rather than on the state of their health).

Post-licence monitoring

Clinical trials test medicines under strict conditions, but in everyday life the medicines will be taken by people with a wider range of personal and lifestyle differences and we might discover new side-effects or adverse reactions. This is why medicines continue to be monitored (Phase IV in the diagram above) through the Yellow Card Scheme (see Contacts p.14), which compiles reports from health professionals and patients about any side-effects experienced and analyses them.

The ongoing regulation of therapies can seem frustrating and bureaucratic, and there are probably improvements to be made in the resources for approval, but rushing new therapies through is extremely risky. There are a few examples of medicines that have been introduced and then rapidly withdrawn when side-effects became apparent, even after clinical trials. With less testing, more people would be placed at risk. And while on the one hand, people point to the success of AIDS activists in getting trials of anti-retrovirals cut short so that the medicines could be prescribed, on the other hand, the slower and cautious approach of the US licensing body to thalidomide spared that country the thousands of cases of babies born with limb defects that occurred in Europe.

For more information about why and how trials should be done see the Delving deeper? section on p.13

“We owe it to previous participants and researchers who had patience to begin to reduce uncertainty, to carry on and be patient ourselves.”

**Hazel Thornton,
Patient Advocate**

A drop of nicotine may do you good, say scientists

New hope for Alzheimer's sufferers after new treatment 'restores memory in minutes'

Doctor's diary: Miracle cure for Parkinson's?

have found benefit from a much cheaper food supplement called ascorbyl palmitate in the USA and Canada and palmitoyl ascorbate in Europe. An 8oz (220g) tub costs less than £25 from the USA

How do I know what to believe....?

There is no easy test of medical claims, but...

...it is possible to build up a clearer picture of research and evidence to put them in context.

...it helps to be alert to the ways that evidence is distorted by different reports and particularly by people promoting ill-founded treatments.

...there are the important questions discussed in this leaflet that tell you how reliable information about a treatment is (Have results been independently researched and then repeated? Has there been a clinical trial? Has it been published in a scientific journal? What is the treatment licensed for?)

Here are some of the questions asked by charities involved in medical research or in public information when they come across medical claims.

Neurological research charities:

"When we look at claims being made on websites selling treatments, we first consider whether it sounds too good to be true. Because there is no known cure for long-term neurological conditions, for example, we are highly suspicious of any adverts or testimonials claiming to cure."

Sense About Science:

"When claims are made about treatments we look for references to clinical trials and published research papers. If any are given, we follow them up to find out whether the research really shows the benefits that are being claimed. Very often it doesn't. For example, we have seen references to clinical trials that have supposedly been done in someone's private clinic and never published in a medical journal. If research results aren't published in a scientific or medical journal, we have to assume that the research did not pass independent scientific review or that someone is not willing to have their claims scrutinised in this way."

Delving deeper?

Here are useful organisations, websites and resources that can help you to weigh up claims about cures and treatments:

The Cochrane Collaboration www.cochrane.org publishes reviews that explore the evidence for and against the effectiveness and appropriateness of treatments (medications, surgery, education, etc) in specific circumstances. They are designed to help doctors, patients, policy makers and others with choices they face in health care. Reviews use a systematic search strategy, which includes searches for unpublished and non-English records, to provide as complete a picture as possible.

Controlled Trials www.controlled-trials.com allows users to search, register and share information about randomised controlled trials.

Decision Aids www.ohri.ca/DecisionAid has information about making decisions based on the options and outcomes of different treatments.

My Medicine www.mhra.gov.uk/mymedicine is a guide to the life-cycle of new medicines, from their first scientific discovery through to licensing and on-going monitoring.

The National Library for Health www.library.nhs.uk has links and resources of where to go for further information about health matters.

NHS Choices, Behind the Headlines
www.nhs.uk/news/Pages/NewsIndex.aspx examines the science behind the headlines, providing the research background to the science that makes the news.

Testing Treatments: Better Research for Better Healthcare (The British Library, 2006 ISBN 071234909X) is an easily digested account of evidence and medicine by Imogen Evans, Hazel Thornton and Iain Chalmers. It can be downloaded for free from www.jameslindlibrary.org.

The UK Clinical Research Collaboration publications *Clinical Trials: Clinical Trials: what they are and what they're not AND Understanding Clinical Trials* which can be accessed from:
www.ukcrc.org/publications/informationbooklets.aspx.

Reading research papers

It can be difficult to access a research paper you have read about, but if you want to locate the paper a good place to try is PubMed (www.ncbi.nlm.nih.gov/pubmed), a service of the U.S. National Library of Medicine. It includes links to full text research papers for biomedical articles back to the 1950s.

It can be hard even for specialists to read research papers and consider the conclusions reached. If you want to do this, a good guide is 'How to read a paper' by Trisha Greenhalgh (Blackwell Publishing, 2006 ISBN 978140513976) or in the *British Medical Journal*
www.bmj.com/cgi/content/full/315/7101/180.

"I don't know what to believe..." – Making sense of science stories is a guide to explaining how scientists present and judge research and how you can ask questions of the scientific information presented to you. It is available free from Sense About Science at
www.senseaboutscience.org.uk/index.php/site/project/30.

-  **The Alzheimer's Society** www.alzheimers.org.uk is the UK's leading care and research charity for people with dementia and those who care for them. T: 020 7423 3500.
-  **The Association of Medical Research Charities (AMRC)** www.amrc.org.uk is a membership organisation of the leading medical and health research charities in the UK. T: 020 7269 8820.
-  **The Medicines and Healthcare products Regulatory Agency (MHRA)** www.mhra.gov.uk/index.htm enhances and safeguards the health of the public by ensuring that medicines and medical devices work and are acceptably safe. T: 020 7084 2000.
-  **The National Yellow Card Scheme** <http://yellowcard.mhra.gov.uk/> is where to go to report suspected adverse drug reactions and side-effects from medicines. T: 0808 100 3352.
-  **The MND Association** www.mndassociation.org is a charity working to help people with motor neurone disease (MND) secure the care and support they need, while promoting research into causes, treatments and a cure. T: 01604 250505. MND Connect: 08457 626262.
-  **The MS Society** www.mssociety.org.uk funds MS research, runs respite care centres, provides financial assistance, education and training on MS and runs a free-phone specialist helpline. T: 020 8438 0700. Helpline: 0808 800 8000.
-  **NHS Health Technology Assessment Programme** www.nchta.org for independent research information about the effectiveness, costs and broader impact of healthcare treatments. T: 023 8059 5586.
-  **Parkinson's UK** www.parkinsons.org.uk funds research into the cause of Parkinson's, improved medical and surgical treatments, better therapies and equipment, and towards finding a cure. Helpline: 0808 800 0303.
-  **Sense About Science** www.senseaboutscience.org is a charitable trust that equips people to make sense of science and evidence. T: 020 7478 4380

Some of the patient views that inspired this leaflet:

“We have had years of so-called miracle cures, often based on whims and the isolated, freak success story.” **David**

“It is very important that the safety and effectiveness of treatments are evidence-based, otherwise we would be chasing rainbows every day.” **Jane**

“Patients with incurable chronic conditions find optimism and hope in very short supply. This makes them particularly vulnerable to treatments that are supported only by anecdote and rumour.” **Ian**

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“Evidence-based medicine is central to providing the best possible care for people with Parkinson’s. Scientific advances in our understanding of the condition and our ability to treat it must flow through into clinical practice, where they can be used to help make the right decisions about care for each individual.” **Parkinson’s UK**

“This matters to me because over the last 20 years I have been encouraged to try so many expensive drugs or treatments. I would have done better to have a good holiday. It is hope that makes us grab at straws. We need facts not dreams.” **Rita Baillie has MS**

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