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ACTUALITY - ACUPUNCTURE CLINIC
Okay so now I'm going to have a look first at your tongue, if you don't mind …

I did brush it this morning.

That's quite good. Okay now can you tip it up, so I can see beneath and back down? And back out again. Alright. So when you - when I look at your tongue I've noticed three things when you put it out - one, it's somewhat pale, it's not desperately pale but somewhat, it is somewhat wet - meaning it's not a dry tongue, it's not cracked, it doesn't have a thick coat on it - and it's also somewhat swollen - it has little ridges along the side. So all of these …

FORD
I've come to see Nancy Holroyde-Downing at the Traditional Acupuncture Centre in London. She's been practising acupuncture for 20 years and over the course of an hour

we talk about my general health, my likes and dislikes, my sleeping patterns, the night cramp in my left leg, whether I feel hot or cold, and even how many siblings I have. At the end, she tells me, that I might have what she calls post-menopausal yin deficiency. So then it was time to lie on the table and check my pulses…

ACTUALITY - ACUPUNCTURE CLINIC
Is this a pulse that feels thick like a rope or thin like a piece of cotton? Is it a pulse that feels soft or is it something that's more like a guitar string - very wiry?

These are quite poetic descriptions of what you're feeling.

They tend to be. Chinese medicine has a lot of resonance with what they call the entire universe, the celestial world - the mountains, the valleys, the rivers, the lay of the land really. Much of Chinese medicine is going to depend upon a dialogue and a sharing of the experiences of the practitioner and the patient. I want you, at the end of a treatment, to have a pulse that is nicely balanced, quite even, not too hard, not too soft, not too tight, not too flaccid, not too big, not too deep - nice, even all the way.

And can you do that in one session?

Ah well probably not. I mean yes, I can make a difference in the pulse if I cannot I've obviously not given you good treatment. Whether it will hold is another question. So I'm going to now put the needles in, the first of them will be something called stomach 36 in Western parlance and in Chinese it would [Chinese name] and the other one is on the inside above the ankle [Chinese name] or a spleen 6. So here we go with the first point, I will locate it by palpating. Now it's going in. Do you feel that?

Yes.

Now is there another sensation?

Oh yes, there we go.

Now that would be the arrival of the chi - has it dissipated now, it's gone off?

It's gone off, it's like an ache.

That's it.

Yes, it's really not like anything …

FORD
Acupuncture is one facet of traditional Chinese medicine, which also includes herbalism. Its origins date back several thousand years and like many complementary and alternative medicines or CAMs, its practices and enticing metaphors seem a million miles away from the concerns of Western science. However, science is catching up in its understanding.

In this programme, we'll explore the issues around how scientists go about testing something which at first glance, appears very unscientific. Perhaps the millions of

Britons using complementary therapy don't need convincing that they work - and by the way my leg cramps haven't returned since that acupuncture. But evidence is a slippery concept, which few in this field of research agree on.

MONTAGE
In every generation there are scientists who dismiss Newton, there are scientists who dismiss relativity and all the other theories that then become accepted later.

With complementary medicine the whole approach of it is about individualised care.

I think that's just a cliché - a tired cliché on top of it.

You can get any rubbish published, you just go down and down and down and down the food chain, as we call it.

You've got to be sophisticated, you can't treat acupuncture just as if it's some kind of drug.

It's a whole bogus question this thing about evidence - homeopathy works.

FORD
We live in an age of evidence-based medicine. It's the buzz word of the medical profession. It may sound like a tautology - I mean, if medicine is not based on evidence, what is it based on? But the fact is that estimates by the medical profession of the percentage of procedures that have been subject to scientific trials vary between 20 and 80%. Enough to suggest that there is still much to be done to test the theories underlying orthodox medicine.

So it's no wonder that some quarters are calling for more research into CAM, but how should it be done? Dr Kate Thomas is deputy director of the Medical Care Research Unit at Sheffield University. She's spent 20 years searching for the fairest way of testing a therapy.

THOMAS
There's certainly no single measure that we could possibly use, I think there's a whole range of different things that we can use and I think the very popularity of these therapies tells us an awful lot about their success from the patient's perspective. Patients are clearly going, we know, that well over 20 million visits a year for these major therapies and to put that in context I always think it's quite helpful to do that - about 14 million visits are made to an A&E department in a year. These aren't people who are going once and then not going again. And the fact that they're going again suggests to me that it's one very good measure of perceived success. Of course that's very different from what we think about in terms of scientific success.

FORD
And scientific success, the so-called 'gold standard' for the evaluation of medical treatments, is the RCT - the randomised controlled trial. A system designed to get the most objective result possible.

THOMAS
The principles of a randomised controlled trial are that you allocate people to a treatment and compare it to another treatment or to a placebo fake treatment and that people are allocated at random, so that you don't influence the outcome by people choosing the treatment that they're getting. And you're looking for a difference between the two groups, at the end of the day, that you feel confident is not due to who was in the two groups but to the treatments that they actually received.

FORD
One of the earliest pioneers of the RCT was an 18th Century doctor called James Lind. His legacy lives on in the James Lind Library, which documents the evolution of fair tests in medical treatments. Its editor is Sir Iain Chalmers.

CHALMERS
The only defining feature of a randomised trial is the word randomised. You use a technique to try and ensure that you compare like with like. So if you've got two treatments that you want to compare, treatment a and treatment b and the people that you give treatment a to tend to be rather iller than the people you give treatment b to and treatment b looks a lot better, how do you know then that the difference isn't in fact just a reflection of the fact that the people were different going into the two groups initially? Clearly you can make mistakes in that way, as indeed we have done recently in advising women who've been taking hormone replacement therapy that taking it would reduce their chances of heart attack and stroke, it's only since the randomised trials have been done, which are designed to ensure that like will be compared with like that we now know that the advice that was being given to women was precisely the opposite of what in fact the truth is - that in fact hormone replacement therapy increases your chances of having a heart attack and stroke.

FORD
Tell me about the early history of randomised controlled trials - why did people begin to think that this was an important issue?

CHALMERS
Well I think it was because doctors started to ask questions about whether their treatments were doing more harm than good. I mean one of the earliest controlled trials was to test whether or not bleeding and purging people when they were poorly was better than leaving them alone and nature to cure them and in fact that particular controlled trial confirmed what we in these days could guess that bleeding and purging's not a very good idea. But that was what was being done by mainstream medicine in those days.

FORD
Whilst the RCT offers the possibility of objectivity, few CAM practitioners are actively involved in research. We'll hear from some who are, later on, but what is common to many in the complementary and alternative scene, is the view that the randomised controlled trial simply isn't the appropriate tool for finding out if a therapy works or not.

MONTAGE
Evidence is important but I think there are limitations on how it's compiled, you know, and that's the point because where you're dealing with healing you're not having a repeatable result under the same physical conditions because every patient is different, there is plenty of statistical evidence for healing working. In our own centre, for example, we find that about 80% of the patients who come to us tell us that they're better in some way, that's purely anecdotal evidence, I accept that.

It depends who's carrying out these trials but yes I do believe that things should be validated scientifically. If somebody is using an alternative approach to illness of any form or description that you should be able to control by clinical testing what is happening to your patient.

I think that homeopathy is about individualisation, it's quite a difficult subject to research because we treat each person as they come in and there aren't any standard remedies really for a condition - the nearest you're going to get is arnica for bumps and bruises and falls and shock and trauma, which you can pretty much say is a specific remedy for those conditions.

MORRELL
This is one of the huge stumbling blocks - how can you have hundreds or thousands of people at a trial when you're individualising the treatment for every individual patient?

FORD
Peter Morrell is a medical historian at Staffordshire University and a firm believer in the power of homeopathy. He doesn't need evidence of a trial to tell him what he's already experienced and feels that the motivation for investigating CAM is not always pure.

MORRELL
If a person has eczema and they've had eczema for 10 or15 years and you give them some sulphur and they have this two or three times a day, this is a personal story by the way, and then they come to you and say - I'm amazed, my eczema patches are getting smaller and smaller, the itching is disappearing, I feel fantastic, I feel like a seven year old child again. And they continue to improve, I mean it's a whole bogus question - this thing about evidence, you know homeopathy works, it works on individuals for individual totalities, or patient totality, it doesn't work for disease labels and it doesn't work in mass trials but it works for individuals. Another aspect of course is the evidence of mass trials financed by drug companies who have a vested interest in seeing homeopathy destroyed. So I would seriously question the word evidence because I think it's a loaded term.

FORD
The world of research into complementary therapy has its cynics and its zealots - those who feel that science is set on destroying CAM and those who believe only through science, can CAM gain credibility and respect.

ERNST

I believe I'm the true champion of complementary medicine because wherever it goes it will go only somewhere if it's based on science.

FORD
Edzard Ernst, as you might have guessed, is firmly in the science camp. The UK's first and until very recently, its only professor of complementary medicine, is based at Exeter University's Peninsular Medical School. He arrived here 11 years ago from Vienna, where he was in charge of a large well-funded and prestigious medical research department. But his arrival here attracted criticism and controversy before he'd even unpacked his bags. His department has produced about 800 research papers - many of which are reviews of other studies, on therapies as diverse as spiritual healing, acupuncture and mistletoe for cancer. So what has he found?

ERNST
The evidence so far is that complementary medicine doesn't defy proper science. A lot of people 10 years ago and some people even today would say that science shouldn't touch complementary medicine because it will destroy it, complementary medicine cannot be squeezed into the straight jacket of a clinical trial and so forth. I think that's just a cliché - a tired cliché on top of it. Perhaps some people mean that our outcome measures - blood pressure, cholesterol levels, pain or whatever - do not capture the whole patient, that I agree with but there are other and perhaps better outcome measures that we can use in parallel - quality of life for instance or simple patient preference.

FORD
Now critics say that most of your research comes up with negative results - are they right?

ERNST
It depends what you mean by most. It's probably more than 50%, so technically speaking most is the correct word. It's by no means all our research negative, I think we have contributed a lot of positive results to the field. But more importantly my only and most biting argument against that is what do these critics want me to do? Should I falsify my data? I'm awfully sorry that this work doesn't produce always positive results but that's science, everything else is not science.

VICKERS
You've got to be sophisticated, you can't treat acupuncture just as if it's some kind of drug. By the same token you can't treat surgery or psychotherapy or speech therapy or nursing therapy or a whole wide variety of different conventional medical techniques cannot be treated or researched as if they're some form of pharmaceutical.

FORD
Andrew Vickers was a bright young researcher when he left the UK to pursue his research interests in the United States, where he now explores the efficacy of CAMs in treating conditions as diverse as cancer and headache at the Sloane-Kettering Memorial Hospital in New York. Rigorous scientific enquiry he says, can go hand in hand with complementary therapy provided you go about it in the right way and ask the right questions.

VICKERS
Imagine you're a patient with migraine headache and you've had it for 20 years and you take your drugs but you still have a lot of pain during the average month, what you want to know is if I was referred to an acupuncturist would this help me? What we did in our trial was we randomly assigned patients with a history of migraine to either go on with their usual care - in other words to avoid seeing an acupuncturist, I mean after all it might just be a waste of time and it would be inconvenient, or to actually go and have a referral to an acupuncturist to see if they could help the migraine. And then we measured their headache after about a year. What we found was that the headache scores - the amount of pain that patients were in - was reduced by about one third in the patients who saw the acupuncturist and by about one sixth in the patients who just carried on with their usual GP care. Now it doesn't sound like very much but these are people with very severe headache problems and so on average the people who saw the acupuncturist had about 22 or 23 fewer days of headache during the year of the study if they'd received the acupuncture.

FORD
So as a scientist is that proof enough for you that acupuncture can be said to work?

VICKERS
As a scientist what I would say is that one study never stands on its own, you always have to look at the evidence - the big picture - all the evidence that we have.

FORD
Let me put the point of view of some CAMs practitioners we've spoken to who say that the individual nature of the treatment defies scientific scrutiny.

VICKERS
That's absolutely fine, many conventional therapies you individualise care, for example social work or psychotherapy - you don't have every patient come in and say you must ask them these sorts of questions and act in these sorts of empathetic ways. Indeed the trial I was involved in, the practitioners in that trial could treat the patients in any way that they felt was appropriate, so care was indeed individualised. And I think the proof really is in the pudding here - if you look in the medical literature you can find extremely standard clinical trials on complementary medicine, you'd read those, you'd think they were entirely fair, they were a good idea and they do give you information on which you can base a clinical decision - whether something works or whether it doesn't. And some of those have found that complementary therapies do indeed seem to help.

MUSIC

PATIENT
This is a wonderful story because I have suffered from hay fever and its symptoms for over 25 years. And I had a particularly difficult day one day, after sawing paduak, which is a hardwood. And I found myself sneezing and coughing and the remedy was what you might describe as potentised paduak - the actual wood dust that was causing me the problem. And I took it that evening and the next day my mates were completely surprised because really I wasn't coughing anymore, really wasn't spluttering, my eyes were clear, everything seemed to have disappeared and that was

all I was interested in - something that would cure me and I was very pleased that it did.

FORD
These stories of apparently miraculous cures come up again and again from patients who have responded dramatically to a CAM treatment. And until recently experiences like this were ignored by researchers or dismissed as anecdote not evidence, but do they have to be mutually exclusive ?

Research-practitioner George Lewith thinks not, and that more emphasis should be placed on patients' stories if we're to better understand the subtleties that might govern if and why a therapy is working.

LEWITH
One of the questions which would be very relevant to ask is what is it about complementary medicine that you really value. What is this subtle thing that you're telling us and how can we measure it? Maybe they value the process of having somebody sympathise with them about their pain. Maybe they value the process of being cared for. Maybe they feel something is being done. Maybe it's more subtle than that, maybe their pain may not be getting better but there maybe something very subtle about their wellbeing that's getting better. Because this is a kind of general phenomena.

FORD
And yet you can see that your critics would take that up and say well this is so airy fairy, even the patients don't know, they just say well I feel a bit better, yet it isn't scientific at all.

LEWITH
Well if you've got a proper diagnosis and you're dealing with a benign condition and you don't have an acute remedy or a competent conventional treatment to offer and you can make your patients better then that's a pretty good treatment really. There's lots of homeopathy being sold in the shops, you can walk into any high street chemist you get homeopathy. The evidence for homeopathy in clinical trials is a bit flaky and it's probably more positive than negative but it isn't strong.

FORD
But the dissolution of a substance in so much water that it doesn't exist anymore, which is what homeopathy seems to be, is very questionable presumably - scientifically.

LEWITH
It's scientifically very questionable because we don't have a mechanism but we have lots of people buying homeopathic remedies, lots of people saying that they feel much better on it and these often aren't stupid people. So what's happening? They're perceiving a benefit which we're picking up in our studies but we're finding very difficult to demonstrate in clinical trials.

FORD
This patient-centred approach to research isn't new but it's still rare says Iain Chalmers, who fears that research questions need to address the needs and concerns of the patient, as much as those of the researcher.

CHALMERS
Researchers left to themselves sometimes address questions which aren't important to patients and even if they choose a question which is important to patients they may not address it in a way that's helpful to the patients at the end of the line. One example is some comparisons of epidural analgesia during labour - pain relief during labour - with alternatives to epidural analgesia where out of about 12 trials only two asked women what pain they were experiencing during their labour and the researchers were into measuring things to four decimal places in the urine and in their blood.

FORD
It sounds quite extraordinary that they could actually overlook that this might be happening to a patient who happened to be a woman.

CHALMERS
It's quite extraordinary and that's why I think it's quite important for patients themselves to help researchers design better control trials, better research, asking sensible questions, important questions, regardless of whether those questions are of any interest to industry or not.

MCPHERSON
If we do artificial treatments then there's a very high risk we're going to show no effect. But if we trust practitioners and set up a trial that is modelled on good acupuncture then those risks are minimised.

FORD
Many CAM practitioners view researchers with scepticism and more than a little suspicion. But acupuncturist Hugh McPherson, who worked with scientist Kate Thomas in Sheffield, says practitioners have to get involved in order to ensure that research is based on therapies as they are practised in the real world.

MCPHERSON
Real practitioners, everyday practitioners, need to be involved in research in order to set the agenda and to argue for the sort of acupuncture that we do, rather than sit back, see other people doing research and of course there are a lot of people who have not very much idea about acupuncture, if we set up acupuncture trials because they perhaps have accessed a patient or they have a particularly good idea - Oh why don't we try acupuncture for such and such. And I think it's much better for us as practitioners to be involved because we can help guide which conditions we should be targeting first, how to treat them and set up a trial design which is going to show the sorts of benefits of our treatments.

THOMAS
It's a big risk for these practitioners. The back pain trial we were doing with acupuncturists was probably three months into the beginning of the trial when Hugh

McPherson turned to me and he said - This trial might not show that acupuncture works. And it was the first time it had really hit him that it might not because like other practitioners they believe in what they do. And it struck me then at that point what a big risk people are taking to be involved in these kind of trials and I'm full of admiration that they do so and I think it's just important that they understand that if people from outside - like myself - or researchers are going to come in and evaluate what they're doing that we're going to evaluate it in its optimum form, as it's practised by them in its best form and the measures that we're going to use are ones that feel appropriate to them. And so they feel it's been a fair test because that's all they're asking for at the end of the day. I don't think they're against having what they do tested, I think they're very wary of it not being a fair test.

FORD
How you carry out a trial in complementary or alternative medicine is one part of the story. What happens with the results is another.

SMITH
With medical research you can get anything published, there are so many journals and have been for a long time. Nobody knows exactly how many there are but there's probably something like 15 to 20,000 and you - to be honest you can get any rubbish published, you just go down and down and down and down the food chain, as we call it.

FORD
Where a study is published doesn't just confer prestige but these days can also influence further funding of more studies. Mainstream medical journals are not exactly awash with CAM papers but an increasingly steady trickle appear in publications like the Lancet and the British Medical Journal, where Richard Smith was until recently, editor.

SMITH
My impression is that we have many more studies of complementary medicine submitted to us, that probably 10 to 15 years ago we got hardly any, whereas now we might get 20, 30, 40 a year, we get about 8,000 papers a year submitted to us, so it's still a comparatively small proportion of everything that's submitted. So I suppose we get about 30 or 40 a year, we probably publish 5 to 10 a year. We know that our readers are very interested in complementary medicine, although there are some of them that continue to be strongly biased against it, there are many more who want to be open-minded on the subject. A point I think it's important to make - I do feel there's sometimes a bit of a catch 22 for researchers in complementary medicine because orthodox practitioners say to them you need to do research to establish whether your treatments work but then it can be very difficult to get the funds to do the research. But without funding and without professional support it can be difficult to do good research and good trials.

ERNST
If you cost clinical trials in complementary medicine they come out very often more expensive than in conventional medicine. For instance, if you do a trial with acupuncture you need acupuncturists and you need repeated treatments and it's rarely possible to do a trial under say £200,000 and that's a lot of money in complementary

medicine. We've actually surveyed what medical charities dedicate to complementary medicine and what indeed the NHS dedicates towards research of complementary medicine, in both cases it's far less than 1%. Compare this with 25% of the population using it this is dismal, this is very disappointing.

FORD
In spite of the cost, thousands of studies have been published on a wide variety of treatments, in a range of journals. And yet for every study that says one thing, another seems to say the exact opposite. But then why should CAM be treated differently from the rest of science? There may be as, Edzard Ernst suggests, only room for a scientific approach when it comes to doing a trial, but interpreting the data is still controversial. More opinion than fact.

However, there's another shadow looming over the growing mountain of research papers. And that's the question of mechanism. Sooner or later, says Kate Thomas, when enough papers conclude that something does work, it still leads to the even bigger question - how does a therapy work? It's a scientific odyssey that has created and destroyed careers and is something we'll explore more closely in next week's programme.

MUSIC

THOMAS
That's the challenge for the scientific community really - how far do we need to know the precise mechanisms of action before we can accept the evidence that they seem to be working? And I suspect we're in for a bit of a challenge. The more we use conventional methods and demonstrate that complementary therapies are working and giving benefit the more we'll be called upon to answer the question about how and why.