

Before I move into the evidence on efficacy and effectiveness, let me talk a little bit about the benefit we measure in patients. So when we measure an outcome, we include a lot of different aspects. We see in our data aspects of the study setting. We see in our data just statistical artifacts, like regression to the mean. Then the whole area of the non-specific effects, including expectation, beliefs, interaction of patient and practitioner. Then, due to the fact that we penetrate the skin and we even rotate manually the needles as you have seen in the video by George Lewis. So we have all the physiological effects here. And last, not least, we have acupuncture point-specific effects.

So now when we use control groups it depends on the control we use for what we control. When I use a penetrating sham acupuncture, I have in my control everything besides acupuncture-point specific effects. So I'm focusing on the acupuncture-point specific effect only. When I use a non-penetrating sham, I have both things in my data, the acupuncture-point specific effect, but also the physiological effects due to the skin penetration. And if I have no treatment control, I include also all non-specific effects in my results and I have to be aware of this.

And that's why I've just labeled here as, "Efficacy 1, Efficacy 2", and the other one I would prefer to call Effectiveness because this is usually done in much more pragmatic trials. So bringing this into the aspect of clinical research questions, when we usually go for a specific effect we do the sham control trials. And in sham control trials we mainly have focus on efficacy.

When I use efficacy here I mean we are going for an ideal situation of our study setting, for an effect in ideal circumstances. Everything is very standardized. Whereas when I go for effectiveness, I usually want to see if something works in usual care in a real, normal less standardized setting. So, effectiveness would be much more when I add a treatment to a usual case setting, and then I perform my study in a usual care setting. And then, I look mainly for an overall effect. Everything is more pragmatic, patients are more heterogeneous, and I can also do studies where I compare to standard treatment, and they are very often in the middle here. They are not really on the efficacy side, they are often not really on the effectiveness side.