

# Methodological issues in evaluating auricular acupuncture therapy for problems arising from the use of drugs and alcohol

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Auricular acupuncture is an accessible, non-confrontational therapy that appears to be effective when used in drug and alcohol treatment facilities, hospitals and prisons in the UK, Europe and the USA. Despite being popular, research evidence on its effectiveness is lacking, and as a result services are underfunded and risk being withdrawn.

There are methodological problems in researching auricular acupuncture. In these days of evidence-based medicine, most studies in this area are explanatory randomised controlled trials, which is limited in capturing the complete benefits of the intervention. Furthermore, there is lack of consensus over definitions of the concept of 'addiction' and whether or not this should be perceived as a 'disease' that can be 'cured' by an intervention such as auricular acupuncture. Basic concepts such as these need to inform development of outcome measures, which should include retention of clients in treatment as an indicator of success.

It is argued here that the best approach will integrate research on physical effects with research on subjective experience of those with drug and alcohol problems. The challenge is to design large scale, high quality, pragmatic randomised controlled trials to assess the effectiveness of auricular acupuncture over the longer term in settings that mimic the delivery of treatment in practice and are informed by acupuncture's own diagnostic traditions, using a combination of objective, quantitative methods and subjective, qualitative methods.

## INTRODUCTION

Auricular acupuncture therapy involves the insertion of needles into the surfaces of the auricles. The idea of stimulating the external ear to treat ailments has ancient roots, being recommended in Chinese texts over 2000 years old.<sup>1</sup> This method was also used by the ancient Greeks, Egyptians and Persians, with Hippocrates making reference to it.<sup>2</sup>

Auricular acupuncture can be understood according to Western medical acupuncture as stimulating nerve or connective tissue,<sup>3</sup> including sensory nerves that influence the release of neurotransmitters at sites throughout the central nervous system.<sup>4</sup> Evidence suggests that acupuncture releases endorphins and enkephalins,<sup>4-6</sup> and may modulate dopamine release via the  $\gamma$ -aminobutyric acid mechanism.<sup>7-8</sup> This may lead to reduction of cravings through blockage of drug receptors and resulting interruption of cravings for drugs, which ultimately may be permanent. *Qi* meridians, as described according to Chinese

medicine, are said to congregate in and have connections to the ear.<sup>2</sup> Thus, according to Chinese medical theory auricular acupuncture stimulates the movement of *Qi* through the meridians and facilitates homeostasis.<sup>2</sup>

Auricular acupuncture is used to combat drug and alcohol problems, is popular among the recipients of this therapy and is used extensively in drug and alcohol treatment facilities, hospitals and prisons in the UK, Europe and the USA.<sup>9-12</sup> It is relatively easy for clients to access and is a largely non-verbal, non-confrontational intervention. There is no need to remove clothing (other than hats covering the ears) or to assume awkward or undignified positions. It is usually provided in a group setting and requires few resources, so it is arguably a relatively cost effective intervention that also facilitates constructive group therapy. Five 'detoxification points' are in standard use: *Shenmen*, Sympathetic, Kidney, Lung and

Liver.<sup>13</sup> However, additional needles can be inserted to treat specific symptoms. For example, for those people who suffer from the substance-use related liver condition Hepatitis C, extra points may be stimulated. Thus, varying treatment plans may be suggested by the practitioner depending on the needs of the client. Typically needles are left inserted for 40 min.

Our clinical experience is that, following treatment, calmness and psychological and physical vitality are experienced with people reporting vastly improved sleep and feeling more energised. Experience also suggests other benefits including: attenuation of cravings and withdrawal symptoms, reduction of body pains, cessation of nightmares, reduction of depression, reduction of irritability and anger, reduction of hyperactivity and reduction of general anxieties. Evidence supporting these effects comes from a randomised controlled trial (RCT) of auricular acupuncture for anxiety prior to dental surgery, which found that auricular acupuncture (intervention group, n=19) and intranasal midazolam (control group, n=19) were similarly effective.<sup>14</sup>

The success of auricular acupuncture is often that clients are retained in drug and alcohol treatment facilities, so they are willing to agree to try other treatment options and to be inspired to improve their health in general. In our own experience, when the auricular acupuncture service at an NHS community drug and alcohol team facility closed, clients stopped attending the other services at the facility, such as one to one counselling and the relapse prevention group meetings. However, despite the apparent benefits of auricular acupuncture therapy for detoxification from the use of drugs and alcohol, there is a lack of convincing research evidence. This results in lack of funding and subsequent lack of availability of therapy. Methodological issues in designing research studies into acupuncture are the subject of ongoing debate<sup>15</sup> and are discussed below.

**METHODOLOGICAL ISSUES**

In the current era of evidence based medicine, studies evaluating auricular acupuncture for substance use problems are usually RCTs that test efficacy. Hammerschlag<sup>16</sup> highlighted the distinction between different types of controlled trials of acupuncture and concluded that based on methodological considerations, when evaluating the efficacy of acupuncture from results of controlled clinical trials, acupuncture has been undervalued in a substantial majority of such trials. Hammerschlag<sup>16</sup> poses the question as to whether acupuncture can be perceived as a standardised biomedical intervention, as opposed to being delivered on the basis of condition-specific diagnoses as informed by Chinese medicine Vincent and Lewith<sup>17</sup> discussed methodological problems arising from the use of placebo control groups in acupuncture research, including unresolved issues in defining an appropriate placebo control, leading to the use of inappropriate controls which give rise to serious misinterpretation of clinical trial results. Given the Western medical acupuncture model suggesting that needles stimulate nerves wherever they are inserted, it could be argued that there are no actual placebo (or 'sham') acupuncture points. So maybe, as with other physical interventions such as physiotherapy, realistic, placebo controls for acupuncture do not exist and blinding is not possible.

From a methodological perspective, explanatory RCTs of efficacy demand tightly controlled experimental conditions and often incorporate a placebo control arm. Thus, extraneous, potentially confounding variables that may impact upon the outcome are excluded. However, when those interventions are applied in actual practice settings they may not perform in the same way as they did under highly controlled, experimental, conditions. The opposite can also be true when attempting to assess the efficacy through placebo controlled trials of what appears to be an effective intervention in actual practice. Auricular acupuncture is an example of such an intervention, and so is likely to be best

evaluated using pragmatic RCTs which assess effectiveness in conditions that reflect actual practice, which may include an 'existing treatment' control group and which concentrate on clinical significance, not just statistical significance.<sup>18</sup> Such studies may demonstrate effectiveness but may not tell us exactly how auricular acupuncture works. But even drugs, which are highly amenable to testing by placebo controlled RCTs, may be acceptable even if the mechanism of action is not known, for example, general anaesthetic agents such as Propofol.<sup>19</sup> This lack of information on mechanisms has never prompted the comment that until we fully understand how general anaesthetics work we should not be giving them to patients undergoing surgery. On the contrary, this criticism has often been raised about acupuncture treatment.

Many RCTs of auricular acupuncture have attempted to assess efficacy, by administering a fixed course of acupuncture treatment over a relatively short time period. Gates *et al*'s<sup>20</sup> systematic review of auricular acupuncture for cocaine dependence included seven RCTs, of which four provided treatment for 8 weeks, one for 6 weeks, one for 1 month and one for 20 days. In addition, a standardised, formulaic approach was used whereby all participants in each study had acupuncture in exactly the same ear points, when in reality, acupuncture treatment is often individualised. Not surprisingly, given these relatively short periods of treatment administration, none of the studies reviewed by Gates *et al*<sup>20</sup> demonstrated a statistically significant reduction in cocaine use.

Furthermore, Gates *et al*<sup>20</sup> noted a considerable number of dropouts who were considered as 'treatment failures'. Dropouts are often high in the area of drug and alcohol services, and clients commonly make several attempts at adherence to treatment and if they do not succeed the first time it does not mean they will continue to fail. Experience indicates that it can take several attempts over several months or even years before some clients adhere to treatment and experience benefits. Thus,

the short-term success of auricular acupuncture should not be overestimated, and studies should have long intervention periods.

A systematic review of publications over the last three decades on acupuncture treatment for opiate addiction found no significant evidence from randomised, controlled, blinded studies that acupuncture was more effective than control treatment, whereas some positive evidence was provided by uncontrolled, open studies.<sup>21</sup> Another concern is lack of consensus over definitions of 'addiction', including whether or not it is a 'disease' that can be cured by medical intervention.<sup>22 23</sup> Even the WHO International Classification of Diseases<sup>24</sup> lacks a definition of 'addiction'. Also, how 'addiction' differs from 'dependence' and whether they should mean physical dependence or psychological dependence or both, are issues that remain unresolved.<sup>22 23</sup> As Confucius rightly pointed out: 'knowledge can only begin when we call things by their correct names'.

Therefore, greater thought needs to be applied to development of appropriate definitions which will inform better outcome measures. To assume that auricular acupuncture can cure the 'disease' of addiction may once again be overstating expectations.

Despite healthcare practice being focused on evidence of effectiveness, Grypdonck<sup>25</sup> argues strongly for qualitative research on human experience of living with chronic illness (such as that caused by problematic drug and alcohol use). Research strategies comprising a combination of objective, quantitative methods and subjective, qualitative methods are needed to develop new outcome measures and optimal treatment protocols, making good use of client involvement and input. Building on Sackett *et al*'s<sup>26</sup> original definition of evidence based medicine, Haynes,<sup>27</sup> stated that patient values should be incorporated into decisions about treatment.

Healthcare is concerned with physical outcomes combined with psychological mediating processes.

Subjectivity and interaction between client and practitioner are important, as acupuncture cannot be delivered in isolation, as if by a robot. The whole treatment experience includes the informal support networks that arise around auricular acupuncture clinics, clients' experience of receiving attention and being cared for by practitioners who address all their needs, for example, by treating additional ear points to alleviate the symptoms of Hepatitis C. Thus, clients are more likely to feel valued, more likely to acquire a sense of purpose in attending treatment sessions (instead of going to drink alcohol or take drugs), are more likely to remain in treatment and accordingly reorganise their daily activities, restructure their lives and redefine their sense of identity.

## CONCLUSION

Auricular acupuncture is a non-confrontational therapy that appears to be effective and is well received by service users. However, funding is limited and is likely to remain so unless positive benefits are more explicitly demonstrated through future research.

Therefore, the challenge, as Hammerschlag<sup>16</sup> rightly emphasises, is to design evaluative research whereby conditions closely mimic the delivery of auricular acupuncture in actual practice, informed by its own diagnostic traditions. This challenge can be addressed through large-scale high quality pragmatic RCTs which focus on the effectiveness of the whole experience of the provision of auricular acupuncture in clinics, compared to other types of treatment across longer time periods, instead of focusing on unrealistic placebo-controlled efficacy studies of relatively short duration. Outcome measures should include retention of clients in treatment as an indicator of success. The effectiveness of formulaic treatment versus individualised treatment also warrants further investigation.

We also need qualitative studies that acknowledge that clients' 'reality' is highly subjective, to provide greater insight into the lived experience of people with drug and alcohol problems and what treatment works best for them. Not least, studies combining objective, quantitative methods with qualitative methods need to be undertaken. Research is also required into the cost-effectiveness (health economics) of auricular acupuncture provided in group settings, as this is likely to compare well against other types of treatment. Such research is currently being planned, based upon collaboration between the Confucius Institute at London South Bank University and Turning Point, one of the largest and most successful providers of substance misuse rehabilitation services in the UK. Those interested in expanding upon this collaboration are welcome to contact the author.

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## REFERENCES

- Chen P. *Modern Chinese Ear Acupuncture*. Massachusetts Taos, New Mexico: Paradigm Publications, 2004.
- Nogier PFM. *Treatise of Auriculotherapy*. Moulins-les-Metz: Maison Neuve 1972.
- White A; Editorial Board of Acupuncture in Medicine. Western medical acupuncture: a definition. *Acupunct Med* 2009; **27**:33–5.
- Andersson S, Lundberg T. Acupuncture – from empiricism to science: functional background to acupuncture effects in pain and disease. *Med Hypotheses* 1995; **45**:271–81.
- Clement-Jones V, McLoughlin L, Lowry PJ, et al. Acupuncture in heroin addicts; changes in Met-enkephalin and beta-endorphin in blood and cerebrospinal fluid. *Lancet* 1979; **2**:380–3.
- Liang J, Ping XJ, Li YJ, et al. Morphine-induced conditioned place preference in rats is inhibited by electroacupuncture at 2 Hz: role of enkephalin in the

- nucleus accumbens. *Neuropharmacology* 2010; **58**:233–40.
- Yoon SS, Kwon YK, Kim MR, et al. Acupuncture-mediated inhibition of ethanol-induced dopamine release in the rat nucleus accumbens through the GABA<sub>B</sub> receptor. *Neurosci Lett* 2004; **369**:234–8.
- Yoon SS, Kim H, Choi KH, et al. Acupuncture suppresses morphine self-administration through the GABA receptors. *Brain Res Bull* 2010; **81**:625–30.
- Berman AH, Lundberg U, Krook AL, et al. Treating drug using prison inmates with auricular acupuncture: a randomized controlled trial. *J Subst Abuse Treat* 2004; **26**:95–102.
- Mitchell ER. *Fighting Drug Abuse with Acupuncture – The Treatment That Works*. Berkeley, CA: Pacific View Press, 1995.
- Wen H, Cheung S. How acupuncture can help addicts. *Drugs Soc* 1973; **2**:18–20.
- Wager K, Cox S. *Auricular Acupuncture and Addiction*. Edinburgh: Churchill Livingstone, 2009.
- National Acupuncture Detoxification Association (NADA). NADA Protocol. 2010. <http://www.acudetox.com/nada-protocol/about-nada/12-faqs.html> (accessed 19 November 2010).
- Karst M, Winterhalter M, Münte S, et al. Auricular acupuncture for dental anxiety: a randomized controlled trial. *Anesth Analg* 2007; **104**:295–300.
- MacPherson H, Hammerschlag R, Lewith GR, et al., eds. *Acupuncture Research: Strategies for Building an Evidence Base*. Edinburgh: Churchill Livingstone, 2008.
- Hammerschlag R. Methodological and ethical issues in clinical trials of acupuncture. *J Altern Complement Med* 1998; **4**:159–71.
- Vincent C, Lewith G. Placebo controls for acupuncture studies. *J R Soc Med* 1995; **88**:199–202.
- Schwartz D, Lellouch J. Explanatory and pragmatic attitudes in therapeutical trials. *J Chronic Dis* 1967; **20**:637–48.
- Astra Zeneca. Propofol (Diprivan) Information Sheet. 2010. <http://www.astrazeneca.com/Medicines/Neuroscience/Product/Diprivan> (accessed 1 Nov 2001).
- Gates S, Smith LA, Foxcroft D. Auricular acupuncture for cocaine dependence. *Cochrane Database of Systematic Reviews* 2006, Issue 1. Art. No.: CD005192. DOI: 10.1002/14651858.CD005192.pub2.
- Jordan JB. Acupuncture treatment for opiate addiction: a systematic review. *J Subst Abuse Treat* 2006; **30**:309–14.
- Cowan DT. Problematic terminology for problematic drug use. *J Opioid Manag* 2006; **2**:23–30.
- Cowan DT. The Great Debate Revisited. *BMJ*. Rapid Response 2010. [http://www.bmj.com/content/340/bmj.b5683/reply#bmj\\_el\\_230884?sid=03c106ae-0dfe-476b-96fe-c2c74b552a31](http://www.bmj.com/content/340/bmj.b5683/reply#bmj_el_230884?sid=03c106ae-0dfe-476b-96fe-c2c74b552a31) (accessed 26 Feb 2011).
- World Health Organization. International Classification of Diseases Tenth Revision. Vol 1. Geneva: WHO, 1992.
- Grypdonck MH. Qualitative health research in the era of evidence-based practice. *Qual Health Res* 2006; **16**:1371–85.
- Sackett DL, Rosenberg WM, Gray JA, et al. Evidence based medicine: what it is and what it isn't. *BMJ* 1996; **312**:71–2.
- Haynes RB. What kind of evidence is it that evidence-based medicine advocates want health care providers and consumers to pay attention to? *BMC Health Serv Res* 2002; **2**:3.



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