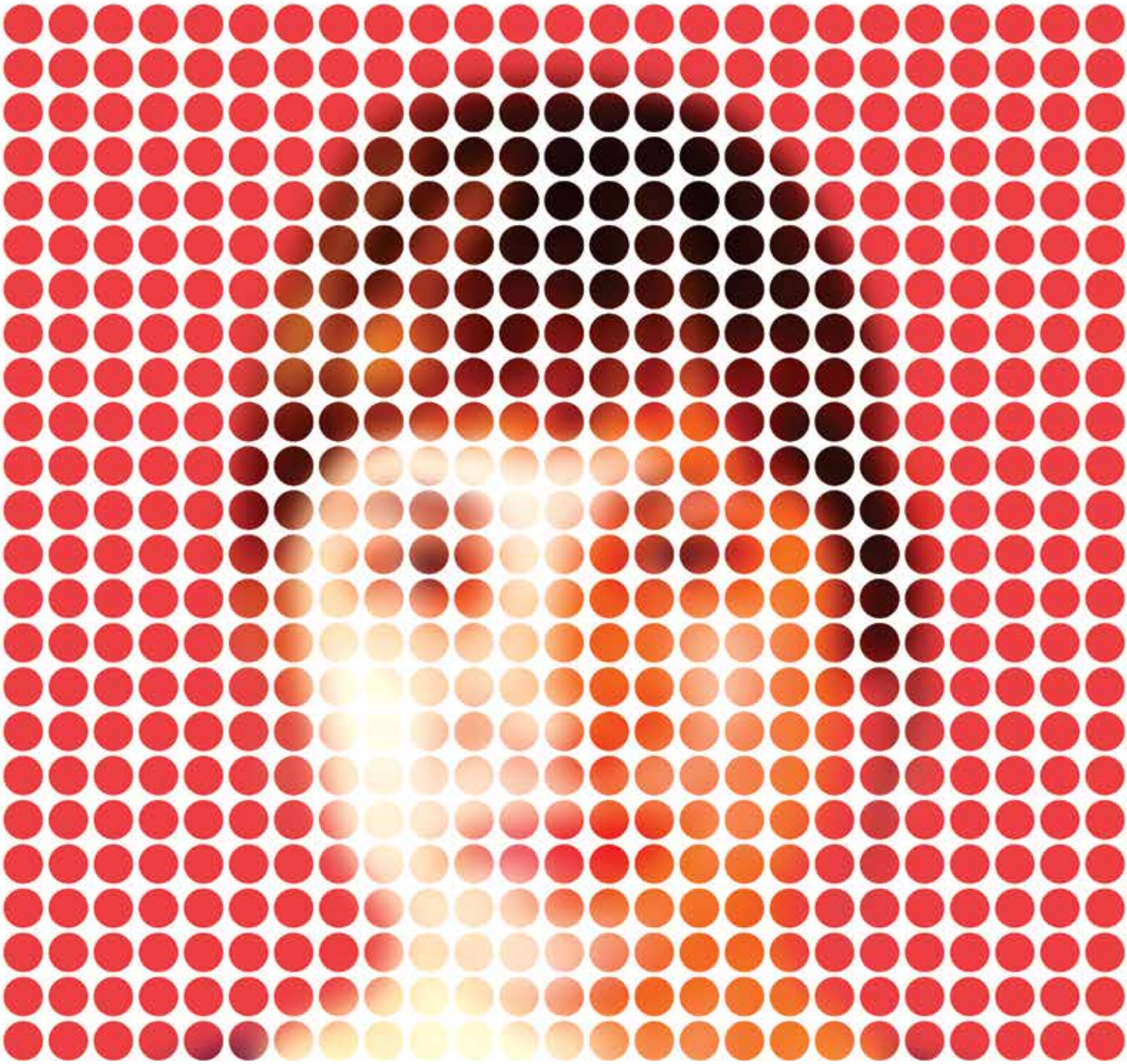

THE HUMAN FACE OF AN RCT

SARA PERREN, *STEWART RICHMOND* AND *HUGH MACPHERSON* REFLECT ON PROVIDING COUNSELLING FOR CLIENTS WITH MODERATE TO SEVERE DEPRESSION IN A RANDOMISED CONTROLLED TRIAL

In recent years, there has been a reduction in counselling provision in primary care; this has been a result both of commissioning decisions resulting from the introduction of IAPT services and of the downgrading of the status of the evidence for counselling as an intervention for depression in the 2009 revision of the NICE Guideline on the treatment of depression in adults.[1] As we move towards the review of that guideline, scheduled for 2015, the advantages of evaluating humanistic counselling are evident in terms of feeding into the next phase of guideline development and informing commissioners regarding whether or not there should be a reintroduction of services.

Because the evidence used by NICE has primarily been based on data derived from randomised controlled trials (RCTs) (the gold standard of evidence), counsellors who have been negatively impacted by the changes have understandably identified RCTs as being the 'enemy' and have believed NICE to be biased against specific ways of providing therapy or of gathering research evidence which may not be suited to the RCT approach.

The *Randomised Controlled Trial of Acupuncture, Counselling and Usual Care for Depression* (ACUDep) was conducted by the University of York and began in 2009. It was designed to compare the clinical and cost-effectiveness of acupuncture, counselling and usual care for moderate to severe depression. In order to ensure each intervention was clearly delineated, the counselling was to be exclusively humanistic and the acupuncture intervention limited to traditional Chinese medicine (TCM). Thirty-seven counsellors took part in the trial. This made it a good opportunity to look at the experiences of the counsellors participating in it, hearing about what they learnt and ascertaining whether their perspectives on RCTs (both methods and results) were changed by their participation.

We hope that the ACUDep study will make its contribution to the evidence evaluated by NICE in 2015 for the effectiveness of humanistic counselling and acupuncture for the treatment not just of mild to moderate, but of moderate to severe depression.

THE TRIAL AND ITS FINDINGS

From the outset, the plan was to compare both acupuncture and counselling with usual care. This was a pragmatic trial – one which aims to closely replicate the conditions under which people seek and receive help for psychological distress within the real world.

Seven hundred and fifty-five people with moderate to severe depression were recruited. To be eligible, people had to have consulted their GP in the previous five years and been given a diagnosis of depression. At the time of recruitment, their depression had to be moderate or severe as determined by a score of 20 or above on the *Beck Depression Inventory* (BDI-II).[2] Staff from the University of York randomly allocated eligible volunteers to one of the three groups in a ratio of 2:2:1 to receive up to 12 sessions of acupuncture, up to 12 sessions of counselling, or usual care alone. Those participants allocated to counselling were referred to a counsellor on the basis of geography and availability.

The clinical results of the trial showed statistically significant beneficial effects of both acupuncture and counselling in the short to medium term.[3]

RECRUITMENT OF COUNSELLORS

The counsellors were recruited to provide treatment within the trial if they were either accredited members of BACP or were eligible for accreditation, which meant that they had at least 400 hours of supervised counselling experience since receiving their counselling qualification. Moreover, as a condition for participating in the trial, the counsellors agreed to provide a humanistic approach to their sessions within the trial.

We hope that the ACUDep study will make its contribution to the evidence for the effectiveness of humanistic counselling

DEVELOPMENT OF THE COUNSELLING PROTOCOL

The humanistic counselling was delivered using the manualised competency framework developed by Roth, Hill and Pilling at the UCL Centre for Outcomes Research and Effectiveness.[4] The trial employed a counselling consultant (SP) who advised on the suitability of the counselling treatment protocol from the practitioner perspective. The competences formed part of the counsellor's guidance manual, which also gave information about trial procedures and their particular responsibilities.

PROCEDURES FOR THE COUNSELLING PROVISION

The counsellors used a logbook to report on aspects of the treatment delivered: the date and duration of each session etc. They were also asked to report on any protocol violations related to the humanistic approach, such as giving advice or direction to clients, setting homework, or suggesting strategies for solving clients' issues. This was to ensure that the humanistic intervention could be clearly differentiated from other structured therapies. Counsellors were expected to take ACUDep clients to supervision in the usual way.

THE COUNSELLORS AND THE CLIENTS

Between them, the counsellors had been in practice, on average, for nine years (with a range of between three and 20 years). Clients were recruited from Hull, North Yorkshire and the North East. The 755 clients in the trial were predominantly female, with a mean age of 44. For 62 per cent, their BDI score indicated 'severe' depression. Sixty-nine per cent were on antidepressant medication. Of the 302 allocated to the counselling arm, 76 per cent of them attended for at least one session; the mean number of sessions attended was nine.

Before people were randomised, they were asked what treatment they would prefer. Fifty-eight per cent stated that they would prefer to receive acupuncture, 22 per cent counselling. We surmise that the reason for the greater preference for acupuncture is that many people had undertaken counselling previously and were interested in a different treatment. Interestingly, analysis indicated that people's initial preference had no significant impact on outcome.

THE INDUCTION MEETINGS

All counsellors and acupuncturists in the trial attended an induction training which offered an overview of the trial, details of the management and protocol, and a CPD session about treating depression. The counselling consultant (SP) assisted in the induction training and counsellors were told they could contact her throughout the trial for support, supervision and advice.

GATHERING COUNSELLORS' EXPERIENCES: THE MID-TRIAL CONSULTATION MEETINGS

Part-way through the trial, we held regional meetings with acupuncturists and counsellors, led by SP and the acupuncturist consultant. Therapists were updated about any changes within the trial, shared experiences and learning, offered each other advice, provided feedback to trial staff, and addressed any concerns.

It was clear from these meetings that therapists were learning how to work within the demands, restrictions and differences of the RCT, discovering what they needed to do differently and clarifying where they were restricting themselves unnecessarily. For example, therapists found that, although the first session was arranged with the client by trial staff, it was helpful to contact the clients themselves. This made for positive intial contact and helped with engagement in the therapy.

Both counsellors and acupuncturists noted that the question they often asked people at the start of treatment did not work well in the trial setting. Although clients had opted into the trial, they had been allocated to counselling by computer rather than having sought therapy themselves. A proportion of them had stated a preference for acupuncture. The customary counsellors' question, 'Why now?' was

not a helpful way to start. Acupuncturists noted that the open question they often ask clients at the start of treatment is: 'How can I help?' This was not an appropriate opening with these depressed clients who could take it as an invitation to tell more of their history than an acupuncturist needs to know. Both groups shared ideas about different ways of beginning the intervention adapted to the particular circumstances of the trial.

Some counsellors were anxious about adhering to the humanistic protocol and were placing restrictions on their style of practice because of the wish to keep to it exactly. This was causing them to feel limited, self-conscious and stilted. We reminded them that this was a pragmatic trial and encouraged them not to assume rigid restrictions but to work as they would in normal humanistic practice. They should therefore not withhold beneficial treatment but note it in the logbook if it fell outside defined humanistic practice. These were valuable meetings and allowed for discussions about each other's practice and priorities for treatment which would have been unlikely to occur in any other setting.

THE QUALITATIVE STUDY

Independently of the data gathered at these meetings, a qualitative study was conducted exploring the experiences of acupuncturists, counsellors and GPs in the trial.[5] As well as exploring experience, recommendations emerged. Some of these are particular to participating in such a trial, others applicable to working with people with moderate to severe depression. Some reflect findings already established by research.

A few examples follow – recommendations are numbered

ASSESSMENT

1 Careful assessment should be undertaken and options discussed with the referring GP before treatment commences

Counsellors noted the importance of careful assessment before commencing treatment and expressed concern that some of those referred with severe depression could have benefitted from a more multidisciplinary team approach. One counsellor commented:

'I think for the severe depression... when a GP is making a referral, if they're in any doubt, then they need a different sort of assessment being done, I think, before they come through to a counselling service. Especially if it's severe depression, because it tends to be a more multidisciplinary team that needs to be involved... And I have worked like that, and it works really well, but it's come from being part of a team.'

DURATION OF TREATMENT

2 Treatment or therapy should be flexible and adapted to the needs of the individual. People who are more depressed may need more sessions than those whose depression is mild to moderate

Where referral was appropriate, counsellors and acupuncturists both felt that 12 sessions was a reasonable length of treatment but wanted the flexibility to offer more sessions – or less – depending upon need and severity.

Counsellors emphasised the importance of pacing the work to suit the individual:

'I mean, I have spent six or seven sessions, just really getting details of things, where others I have taken one. And if I'd rushed that person, they wouldn't have engaged in therapy any more. They would have found it too much.'

MANAGING RISK

3 Contact the GP if you feel your patient is at risk of self-harm or suicide.

Managing risk was more of a dilemma for acupuncturists than counsellors, the latter being more accustomed to, and more confident with, working with risk. Nonethetheless both groups felt the issue of risk was crucial.

'Risk is very high with depressed patients. Particularly check risk. Depending once again, mild to moderate to severe. The more severe, you're looking at risk features quite frequently actually. I check that almost every session until their mood starts to improve.'

WHO MIGHT RESPOND WELL TO TREATMENT?

4 If a referral is inappropriate, refer back to the GP. But also recognise that small changes can be significant when working with people with addictions or chaotic lifestyles. Consider creative collaborations with other practitioners in working with this group of people

In line with already established research findings,[6] all therapists were agreed that people who responded best to treatment were those who showed 'willingness to change' and 'readiness to engage'.

'...to help people take responsibility and realise that there maybe is something that they can do. I think sometimes people get trapped in feeling depressed and feeling unable to do anything. So almost helping empower them to find changes that they can start to make... which over time build up and help them move forward.'

There was shared concern about how best to assist people with addictions and chaotic lifestyles. There was some discussion about whether a shared approach, including both acupuncture and counselling, could be beneficial for this group, and consensus that a further trial to investigate this would be interesting.

ADDITIONAL RESOURCES

5 When working with this client group, consider making appropriate adjustments to working practice

Therapists noted that working with moderately to severely depressed people can be taxing, and additional resources may be needed. For acupuncturists, this could involve seeking supervision; for counsellors, it might involve reducing their caseload.

CONCLUDING REMARKS

While there were obvious differences between counsellors and acupuncturists in the trial, they seemed to share a belief in the benefits of a 'holistic' approach to treating mental distress. Both counsellors and acupuncturists expressed reluctance to diagnose depression as a medical condition. There was also shared concern about depression being treated in isolation without taking into account other factors

in people's lives, such as physical health, social environment, work, economic situation and family and social support. One counsellor remarked:

'You'd think about counselling and acupuncture being very, very different treatments. And yet, philosophically I think a lot of acupuncturists are not in a totally different place to counsellors, you know. They're seeing people in a much more whole way and they're not just focusing in on a diagnosis, you know, in a medical sense.'

Counsellors appreciated the opportunity to take part in the trial. They felt that counselling has an important part to play in supporting and assisting in the recovery of people with mental health problems in the NHS. They felt optimistic that, by participating in the trial, they were making a positive contribution to strengthening the evidence base for counselling. Although they found participating in the trial demanding, they had appreciated the support offered by the counselling consultant and felt that the research team conducting the trial were responsive, communicative and helpful. They valued the collaborative meetings, both for the training offered and the opportunity for conversations and shared thinking between counsellors and acupuncturists that could not have happened otherwise.

Several counsellors said that they had started out with a bias against RCTs, viewing them to be impersonal at best and, at worst, an exercise in manipulating statistics to produce findings supporting the bias of those with vested interests. Participating in this pragmatic randomised controlled trial seems to have persuaded many that RCTs have a human face and can produce meaningful data. They saw that RCTs can be conducted by researchers who demonstrate true curiosity about what the data will show and are committed to analysing and presenting those data with integrity and transparency. ■

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