

# TALKING POINT PAPERS 1

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## Randomised controlled trials: The straitjacket of mental health research?

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# Biography



**Alison Faulkner** is a survivor researcher, trainer and consultant in mental health. Much of her work is connected with involving mental health service users in research.

She has over 25 years' experience of mental health research and consultancy, including working for the Mental Health Foundation, NSUN (the National Survivor User Network), Mind, Together, and the Joseph Rowntree Foundation.

Alison also has experience of using mental health services and has written and presented extensively on the subject from a user/survivor perspective. She is currently working with NSUN on national standards for involvement and is studying for her PhD at City University.

# About the talking point series

Almost everything to do with mental health has been, or is, sharply contested. Everything from understanding health experiences and diagnoses, appropriate treatments and approaches to managing distress, to the language used to describe mental health problems has sparked ferocious debate. Mental health research is no exception. We still have a lot to learn.



To date the majority of the discussions in mental health research have been framed from the point of view of mental health professionals and academics writing in medical journals or speaking at conferences. We welcome these platforms but are keen for discussions to broaden both engaging other disciplines in mental health research more as well as other groups, particularly service users and families. We have therefore commissioned a new series of Talking Point papers to encourage people to consider key issues in mental health research. We start with study design. RCTs are a very important research methodology – what are their strengths and weaknesses? How can we make the most of the RCT design and when are other approaches more useful?

A little bit of background about the McPin Foundation. We are a mental health research charity who wants to see experts by experience involved in all aspects of research. We are committed to improving the quality of mental health research because we need to know a lot more about what works to improve the mental health of communities everywhere. We approach this by championing experts by experience because we believe better mental health research is done collaboratively, including service users and their families.

Our Talking Point series are written from the point of view of someone with lived experience of mental health problems. Topics are chosen by the authors themselves because they are important issues to debate. We hope that each paper will spark a constructive dialogue between a very wide range of people. We also hope that the Talking Point papers will influence the development of future research.

The funding for the Talking Point papers is from the McPin Foundation but the views expressed in the papers are the author's own. We are keen to hear from others who would like to contribute to the series – you can email ideas for topics to [contact@mcpin.org](mailto:contact@mcpin.org).

We are very pleased to present the first Talking Point paper by Alison Faulkner on a study design issue – the Randomised Control Trial. Alison has been working in mental health and enlivening debates with her writing for many years. Methodological issues are crucial to framing quality mental health research.

Join the discussion on this issue through our Facebook page or Twitter (the Twitter Handle is @McPin) and our hash tag for the paper is #RCTdebate and #transformMHresearch. You can also leave comments on a blog article that we have placed on our website ([www.mcpin.org](http://www.mcpin.org)) to announce the launch of this paper.

**Talking point papers give people with lived experience the opportunity to discuss and debate under-discussed or particular difficult issues in mental health research. We hope that these papers, and the discussion around them, will aid us in our mission to 'transform mental health research'. The funding for the Talking Point papers is from the McPin Foundation but the views expressed in the papers are the author's own.**

“The greatest obstacle to discovery is not ignorance, it is the illusion of knowledge.”<sup>1</sup>

1. Boorstin, D.J. (1983) *The Discoverers: A History of Man's Search to Know His World and Himself*. Random House.

Randomised controlled trials (RCTs), and systematic reviews of RCTs, dominate the landscape of mental health research and evidence-based healthcare. This paper has been written with the aim of challenging that domination, and of suggesting that we need to populate the landscape with alternative sources of knowledge and evidence from a survivor researcher perspective. Of greatest concern is that the uncritical reification of the RCT marginalises the knowledge or evidence produced by mental health service users and survivors.

As a survivor researcher, the author contends that survivor research (user-controlled research) has a major contribution to make to the knowledge base about mental health and to the debate about what constitutes acceptable evidence in mental health care.

The existing research structures and the evidence hierarchy, in which RCTs are held to be the 'gold standard', are preventing this contribution from being realised.

## Questions this paper raises include:

- Can mental health and distress be measured meaningfully?
- Are there some interventions for which the RCT model is simply inappropriate?
- What outcomes and outcome measures are valued by service users?
- How can we raise the profile of experiential knowledge?
- How can we work to ensure that different sources of knowledge and evidence are taken into account in mental health research?

## The paper is structured as follows:

- I. The Limitations of RCTs
  1. *What is a randomised controlled trial?*
  2. *RCTs and Evidence-Based Medicine*
  3. *RCTs in mental health research*
  4. *Outcomes and outcome measures*
  5. *Generalisability of findings*
  6. *Ethical issues*
  7. *Bias and objectivity*
  8. *Knowledge and evidence*

- II. Some Potential Ways Forward
  1. *Improving the RCT model*
  2. *Interdisciplinary and mixed methods research*
  3. *Validating different sources of knowledge/evidence*
  4. *Qualitative methods*
  5. *Collaborative research*
  6. *User-controlled research*
  7. *Supporting academic user/survivor researchers*



# The Limitations of RCTs



## 1. What is a randomised controlled trial?

We all benefit to a greater or lesser extent from research that has, over decades and centuries, examined the value of different drugs and other interventions in treating illnesses. History tells us that the first clinical trial was carried out by James Lind, a Scottish naval surgeon, who carried out an experiment on board ship that showed that citrus fruits could prevent scurvy.

Nowadays, the RCT is considered to be the 'gold standard' research design for demonstrating a cause-and-effect relationship between an intervention and an outcome. The core purpose of the RCT is to test the effect of an intervention by comparing a group of people who are given the treatment under investigation with a (control) group of people who are not given the treatment. Central to the method is that people are randomly allocated to the groups to eliminate the effect of external factors.

The aim is to control the conditions surrounding the trial, such that the effects of the intervention can be measured with some degree of confidence. This control is essential to isolating the effects of the intervention from other potentially confounding variables.<sup>1</sup> In a sense this is an attempt to create 'laboratory conditions' for the experiment.

There are obvious advantages to the RCT model. If we want to know the effects of a drug in treating an identified disease, it is essential to see if it makes a difference to people who are given the drug compared to people who are not given the drug. In the process of doing this, we must be sure that the people in both groups are similar, that they are not taking or doing anything that might confound our measurement of the drug's effects. The people in each group must have the same condition and have no other complicating illnesses or factors that might mask the effects of the drug or make our measurement less certain. In a 'blinded' trial, neither the clinician nor the patient will know whether the patient is receiving the drug under investigation. In other words, it is not an easy matter to carry out a good quality RCT.

## 2. RCTs and Evidence-based Medicine

RCTs operate within the context of Evidence-based Medicine (EBM) which maintains that clinical decisions need to be based on the best evidence – a tenet that, on the face of it, is hard to argue with. This can be traced back to Cochrane who argued against the tendency for consultants to base their opinions on opinion and tradition, rather than on evidence. His name now graces the Cochrane database started in the 1990s to collate and appraise evidence from RCTs for use in practice. At the root of evidence-based medicine is the often-quoted hierarchy of evidence (see Table 1) which places RCTs and systematic reviews of RCTs at the top and the views of clinicians and patients at the bottom. Qualitative research has traditionally been placed just above the views of clinicians and patients, rendered almost as powerless to inform evidence.

The RCT has become ubiquitous in considerations about evidence by the Department of Health and the National Institute for Health and Care Excellence (NICE), thereby setting the context for research activity and clinical decision-making. Considerations of evidence by NICE have become a bit more sophisticated over time, with some acknowledgement recently that there are questions for which different methodologies are more appropriate. An example is patient satisfaction, for which they recommend surveys and/or qualitative methods in preference to the RCT. Nevertheless, this type of hierarchy is still alive and well. Even with modifications, the views of service users and carers remain at the bottom of the hierarchy, marginalising the voices of lived experience. And the RCT remains at the top.

Over the years, many researchers have highlighted the limitations of RCTs in mental health research and beyond.<sup>2,3,4,5,6,7,8,9,10,11,12</sup> These limitations range from methodological to conceptual and ethical; they come from clinicians and researchers as well as from service users and survivors. There are both general limitations (relating to RCTs undertaken in any field of enquiry) and limitations that have specific relevance to mental health. The focus in this paper is on the latter, although reference is made to the former.

**Table 1. A hierarchy of evidence**

<b>Type I</b>	At least one good systemic review, including at least one randomised controlled trial
<b>Type II</b>	At least one good randomised controlled trial
<b>Type III</b>	At least one well designed intervention study without randomisation
<b>Type IV</b>	At least one well designed observational study
<b>Type V</b>	Expert opinion, including the views of service users and carers

### 3. RCTs in mental health research

At the heart of the limitations of RCTs for mental health research are the underlying assumptions that arise from the medical model underpinning psychiatry. Decades of research have failed to confirm biomedical explanations for mental illness; diagnoses are unstable and of limited clinical value.<sup>13,14,15,64</sup>

*“I can calculate the motion of heavenly bodies but not the madness of people.”*  
**Isaac Newton**

'Mental illness' cannot be identified or measured directly. There is no blood test or brain scan to assess the type or degree of 'mental illness' and so we are left to rely on 'proxy' measures: diagnostic frameworks, scales and questionnaires that rely on people self-reporting their feelings, symptoms and behaviours.<sup>13,6</sup> The RCT model originated in the natural sciences where the complexity of human beings and their interactions did not feature. In clinical settings, few people fall easily into one diagnostic category without complicating features, symptoms, secondary or amended diagnoses.

This is a major challenge to the use of RCTs in mental health.<sup>6</sup> It undermines the selection of people to trials (because it is impossible to confidently identify people with the same diagnosis or underlying condition); it undermines the extent to which findings can be generalised beyond the trial and it undermines the choice and measurement of treatment outcomes.

### 4. Outcomes and outcome measures

For RCTs to have external validity (for their findings to be generalised beyond the trial conditions), the outcomes must indicate the priorities of patients.<sup>7</sup> Clinicians and patients often value different outcomes and the outcomes valued by patients are rarely measured in RCTs. In mental health, as suggested above, the relationship between 'illness', intervention and outcome is contested by some fundamental differences of opinion, belief and values. A solely biomedical understanding of mental illness will result in an emphasis on symptom relief as the focus of outcome measures, which may not be the priority of service users. This is a problem when it comes to translating the findings of research into clinical settings, where the priorities and experiences of service users become paramount.

The problem with using outcomes not valued by service users is that the findings will be artificially skewed. If questions/items on the unwanted effects of drugs are not included in a measure, clinicians may be surprised when they come to use the drugs and patients do not wish to take them. This is a simplistic example, but a real one. For decades, pharmaceutical companies and clinical researchers have been underestimating the unwanted effects of drugs on people's quality of life, a bias that has resulted in new studies of 'non-compliance' to find ways of persuading people to take the drugs that cause them harm. To this day, many RCTs on medication do not include questions about the unwanted effects, resulting in a failure to take into account key



issues that may make the drug fail when it comes to be used in practice.

This relates to one of the criticisms made by Slade and Priebe<sup>5</sup> who point out that group-level RCT designs, where people are grouped by diagnosis, masks the fact that there are considerable individual differences in response to treatment interventions. They give the example of giving antipsychotic medication to all people diagnosed with schizophrenia, drugs that can be ineffective and potentially harmful for some people.

## 5. Generalisability of findings

A fundamental expectation of RCTs is that their findings will generalise beyond the trial, to the wider population of people with the same condition in order to aid the decision-making of clinicians and, ultimately, the health outcomes of their patients. However, a number of researchers have pointed out that the findings of RCTs cannot be easily generalised to natural conditions, for the very reason that they are artificially constructed situations that do not exist in the real world.<sup>7,11</sup> They fail to address complex social and psychological interventions and healthcare systems.<sup>12,16,11,17</sup>

Wolff<sup>11</sup> suggests that 'socially complex service interventions' violate the assumptions underpinning the simple RCT model in ways that challenge the validity, reliability and generalisability of trial findings. Social and political factors influence the capacity of human beings to behave according to the requirements or indeed the findings of RCTs.<sup>12,6</sup> Attempts to select people with a single diagnosis for inclusion in a clinical trial, again, means that their findings will be difficult to generalise to clinical practice in which most people present with a mixture of complex problems.

In addition, the sample for a trial is sometimes deliberately chosen to be homogeneous, as another way to control for variability. This often means that the sample is white, sometimes male only, and English speaking. This often means that the sample is white, sometimes male only, and English speaking. It is common for people from minority ethnic communities to be excluded

from clinical trials in health research;<sup>18</sup> language, time and resources are often given as reasons for failing to include participants from minority ethnic communities. Questions then arise about whether the findings can be generalised to heterogeneous populations and individuals with diverse characteristics. As pointed out by the US Federal Drugs Agency,<sup>19</sup> drugs can work differently in people of different ages, races, ethnic backgrounds and genders: hence the ethical significance of carrying out trials on predominantly white male participants.

There is another ethical issue here about equity in healthcare provision, since there is evidence to suggest that people who take part in clinical trials have better health outcomes.<sup>18</sup> The issue is more serious than that though, when we consider that certain marginalised and minority communities are over-represented in mental health services; excluding them from research on those same services is an issue of social justice.

There is an underlying assumption in conducting RCTs that any intervention can be treated as if it were a drug: that the intervention will have reliable effects and can be applied in the same way to each person. It is also assumed that each person will receive it in a similar way, which cannot be the case when the intervention is in itself relational or exploratory (as in the case of psychological interventions). Human beings are relational beings; each of us influences the other and is unlikely to react in the same way to the same (or different) people. Canter<sup>12</sup> suggests that the assumptions underlying RCTs place a 'straitjacket' on the theories of human experience and action that can be tested; they 'profoundly limit how we can explain psychological and social processes' (p.1).

## Psychological interventions and RCTs

A major challenge to RCTs has come from the field of psychotherapy, in a significant demonstration of the complex relationship between evidence, policy and practice.<sup>10,12,20</sup> The intervention that best fits the method (Cognitive behavioural therapy or CBT) has come to dominate the field, precisely because there is better evidence to support it. During the period

when statutory registration and regulation of the psychotherapies by the Health Professions Council (HPC) was being considered, many clinicians and researchers made their views known. Some highlighted the inability of RCTs to address complex psychological interventions as opposed to the more easily replicable CBT currently dominating NHS provision of psychological treatments.<sup>10</sup> Randomly assigning patients to therapies or therapists both removes some of the factors that help make therapy successful and renders the treatment intervention at least partly visible (i.e. not amenable to a blinded trial). Furthermore, subjecting a psychological treatment to a RCT means forcing it to become a manualised, mechanistic intervention as opposed to the relational and exploratory process it is intended to be.<sup>10</sup> This raises the question of whether some treatments or interventions are quite simply inappropriate for the RCT model.

## 6. Ethical issues

All clinical research in the NHS is governed by ethical guidelines, based on the principle that participants should not be harmed by research ('non-maleficence') and that the research itself should be for the 'common good' ('beneficence'). The key historical agreement here is the 1964 Declaration of Helsinki, the first international document to set ethical guidelines for research with human participants. Informed consent plays a central role in all such guidelines.

The main ethical issues surrounding RCTs concern the fact that the people who ultimately stand to gain from the trial results are not the same people who are taking part in the trial. In addition, in most trials, there are different issues affecting those individuals who are given the intervention and those who are consigned to the control group. Both could be taking a risk: the intervention might have harmful effects, but if it has positive effects, there are implications for those in the control group who are not given an intervention which proves to be beneficial. These issues potentially affect all trials. The ways in which researchers navigate these issues is to obtain 'informed consent' to participate in the trial. However, this too is fraught with difficulties: are participants given sufficient information? Do they

have capacity to consent? Do they feel obliged to take part in the trial because it is a professional or clinician who is asking them, and they do not feel able to refuse?

A particular issue surrounds the concerns about vulnerability and capacity to consent to take part in research, where potential participants are detained in institutions. Clinical academics might take the position that people should have the right to take part in research,<sup>22</sup> whereas service users and survivor researchers might be more concerned about the potential coercion of disempowered individuals to take part in the research. The issue of potential harm from participating in research is where the significance of informed consent comes in: to ensure that people take part voluntarily with full information about the potential harms and benefits.

In mental health research, a key ethical challenge is the withholding of a potentially effective treatment from someone who is currently in mental distress. The counter to this might be to say that the treatment is not known to be effective until the research has been done, but the fact remains that people who are not randomised to their treatment of choice may experience worse outcomes or withdraw from the trial.<sup>23</sup>

Williams<sup>24</sup> highlights the importance of researchers taking an ethical stance to challenging the social injustices that play out in the research context. Through working with community groups and broadening the ethical basis of research, researchers can ensure the inclusion of participants from minority ethnic communities in health research and work with them to identify relevant research questions.

## 7. Bias and objectivity

A more fundamental challenge to the role and value of RCTs is to question the whole concept of objectivity. When we see the many sources of bias that can creep in,<sup>9</sup> it is hard to see how any single RCT can claim to be objective. Indeed, is objectivity even necessary or desirable? Is it possible within the mental health context fraught by such contested issues as the validity of a medical basis for diagnoses?

*“We are concerned with the danger that RCTs may be perceived as a sort of talisman, to protect us from the evil of bias. But randomized trials are not divine revelations, they are human constructs, and like all human constructs, are fallible.”*  
Jadad and Enkin,<sup>9</sup> p.44

The elephant in the room here is the pharmaceutical industry. Famously, Goldacre<sup>25</sup> points to the plethora of poorly executed trials, many of which are subject to the vagaries of the pharmaceutical industry. Keen to prove the efficacy of a new drug and with profit in mind, they may introduce biases along the whole production line in order to over-state the positive effects of a new drug. These range from not asking questions that might conflict with a drug's potential positive effects, through ceasing a trial that is not 'working' (without recording this), to the failure to publish findings that do not support their requirements.<sup>5,25</sup> Many clinical academics are likely to be similarly influenced if they are undertaking trials of a particular drug funded by industry.

Slade and Priebe<sup>5</sup> point out that all researchers have particular values and beliefs which will lead them to investigate one area or intervention rather than another or to present findings that confirm rather than refute their beliefs. Similarly, Rose<sup>26</sup> points out that all research comes from a particular standpoint (or perspective); she argues for the recognition of different standpoints alongside the challenging of traditional notions of credibility, validity and legitimacy.

Glasby and Beresford<sup>2</sup> reject the idea of 'objectivity' as a necessary pre-requisite for valid evidence. Indeed, they suggest that objectivity and distance (between the researcher and those being researched) can be harmful in some circumstances, leading to the distortion or misunderstanding of the experience being interpreted.

*“The shorter the distance there is between direct experience and its interpretation (as for example, can be offered by user involvement in research and particularly user controlled research), then the less distorted, inaccurate and damaging*

*resulting knowledge is likely to be.”*  
Beresford<sup>27</sup> p.7

Many researchers have demonstrated the value and the benefits to be gained from reducing the distance between researcher and researched, for example as interviewers<sup>28,29,30</sup> and in the analysis and interpretation of results.<sup>28,31,32,33</sup>

## 8. Knowledge and evidence

*“Mental health service users have traditionally been excluded from creating the knowledge that is used to treat us, and many of us have suffered from the misunderstanding of our needs by people who have been taught to see us as by definition incapable of rational thought.”*  
Wallcraft<sup>34</sup> p.133

Methodological limitations aside, the placing of systematic reviews and RCTs at the top of the evidence hierarchy has limiting effects on the nature of the knowledge and evidence produced.<sup>35,2,36,26</sup> There is more 'good quality' research evidence about drugs, thus perpetuating the dominance of the medical model within psychiatric care. First person experiences and small-scale qualitative studies are devalued in relation to the so-called 'objective' evidence produced by clinical researchers. Clinical researchers may or may not engage in deliberate efforts to control this situation, but the reality is that they are supported by the wider social and cultural forces surrounding the production of research.<sup>37</sup>

One of the consequences of this is that the interventions given legitimacy by clinicians and by NICE are those that have been studied using RCTs – primarily, the range of medications used in psychiatry. Reliance on the RCT model continues to undervalue any intervention for which the outcomes are difficult to measure.<sup>38</sup> Although we 'know' that people with mental health problems benefit from a range of psycho-social supports (good physical health, support with relationships, housing etc.), these supports will be the first to go in a funding crisis as there is no 'evidence' to support them. The core of treatment will remain



the same: medication. This perpetuates the dominance of psychiatry in mental health services and serves the pharmaceutical industry very well.

Most significantly, it means that little research space is given to theories that challenge or conflict with the medical model.<sup>39</sup> The reification of the RCT marginalises the knowledge or evidence produced by mental health service users and survivors. How, then, are service users to get their views and voices heard within this system and structure? With difficulty, it would seem. This brings us to the need to acknowledge the power differentials that exist in research production and how they influence the knowledge that is given the most status, authority and funding.<sup>37,39,35</sup>

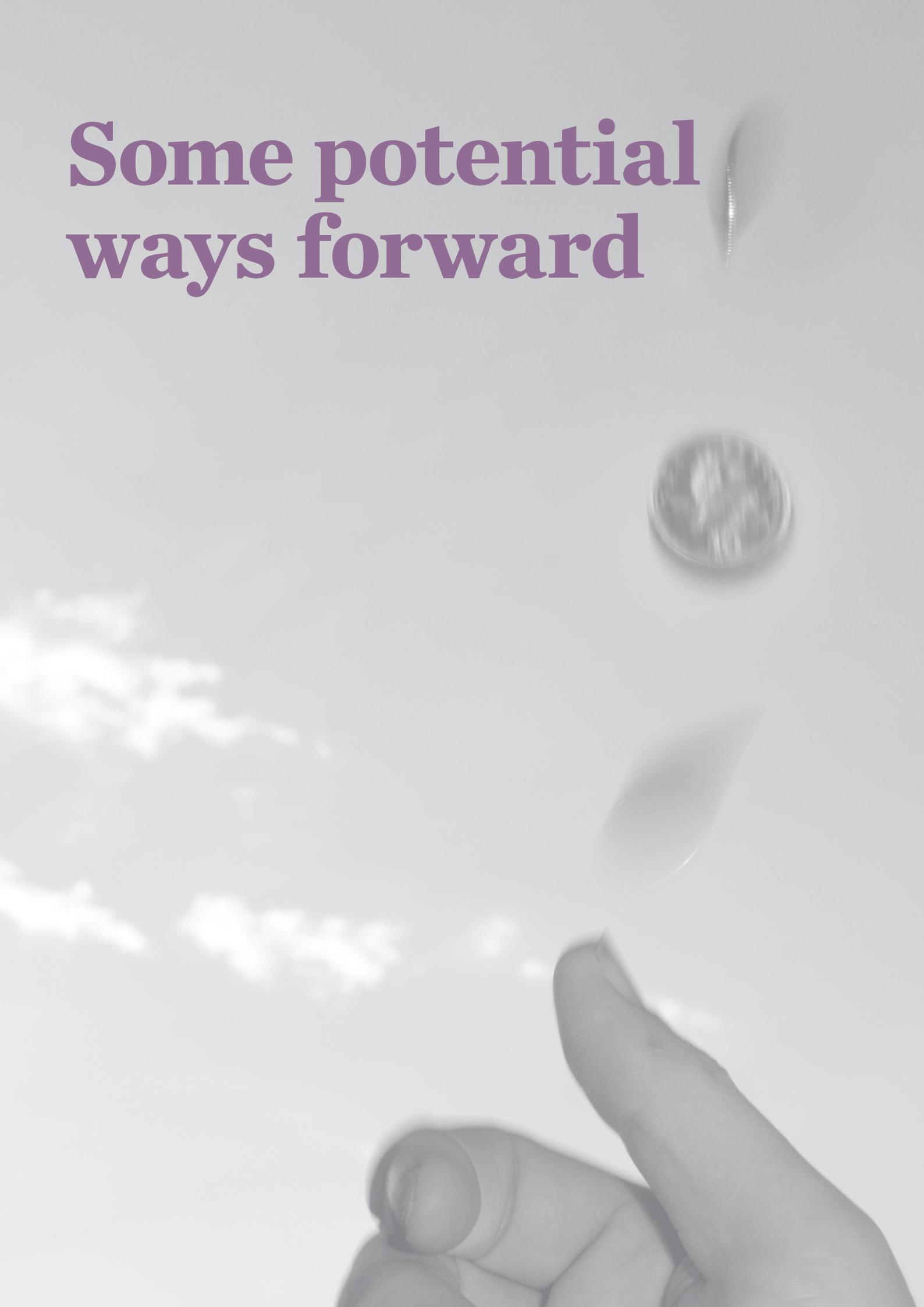
Glasby and Beresford<sup>2</sup> ask some fundamental questions about the nature of knowledge within our evidence-based world. In their view, neglecting the views and experiences of people who use health and social care services gives a *'false and potentially dangerous view of the world'*. They highlight the crucial contribution that this 'experiential knowledge' has to bring to the evidence table, a theme taken up by many survivor researchers.<sup>36,26,39</sup>

For Sweeney<sup>36</sup> experiential knowledge is the 'bedrock' of survivor research, in the collective move to challenge the exclusion of service user and survivor voices from mainstream research and knowledge production. The experiential knowledge gained from direct personal experience of the (mental health) issues under study is what distinguishes survivor research.

Research that enables us and our peers to reflect on our experiences and build and produce experiential knowledge as a means of both capacity building amongst ourselves and critique of professional knowledge, is an essential development of our lived experience of mental distress.



**Some potential  
ways forward**



*If our aim is to obtain better evidence of the kinds of treatments or interventions that work best for people experiencing mental health problems, it seems important to address the issues raised here in relation to our continued reliance on RCTs, and to suggest some alternative ways forward in building meaningful evidence.*

## 1. Improving the RCT model

One approach, advocated by the NIHR, is to carry out bigger and better trials, with the additional need to ensure that trial designs address some of the criticisms made here. Others have suggested different approaches to the design of clinical trials, an example of which are 'patient preference RCTs'<sup>23</sup>. However, these constitute a partial response as they would still omit the knowledge and evidence developed by people in receipt of mental health services, and would perpetuate current understandings of who holds the valid knowledge about mental health services and treatments.<sup>26,35,36</sup>

RCT methods could be improved for use in mental health research by the use of more relevant and appropriate outcomes and outcome measures. Several studies have demonstrated that service users value different outcomes to those assumed and used by clinicians and researchers.<sup>41,42</sup> The ROLE Network (Relating Outcomes to Lived Experience, a service user network based in the North West)<sup>43</sup> reviewed a number of commonly used outcome measures from a service user perspective and concluded that an approach based on capabilities may encourage an holistic view and be more inclusive. Kabir and Wykes<sup>42</sup> highlight the need for good measures of satisfaction, service outcome and quality of life that reflect the mental health service user's experience.

Rose et al<sup>44</sup> and Rose<sup>45</sup> describe a method for developing patient-generated 'Patient Reported Outcome Measures' or PG-PROMs<sup>46</sup>. Greenwood et al<sup>47</sup> highlight the importance of choosing the outcome to suit the intervention, in this case measuring what CBT is actually targeting: not psychotic symptoms directly, but such cognitive

and emotional issues as distressing emotions, anxiety, beliefs about voices, self-esteem and relapse prevention. They recommend that their new measure (CHOICE) complements the need for other psychosis symptom measures in RCTs, and that it provides the opportunity to advance the evidence base for CBTp (CBTp is CBT designed for people with a diagnosis of psychosis) with '*an assessment approach that places service user definitions of recovery at the fore*' (p.133).

## 2. Interdisciplinary and mixed methods research

One way forward seems to be to combine research methods, for example supplementing RCTs with qualitative methods, to include different sources of evidence and ensure that the meaning of an intervention or its context is not lost. Both Greenhalgh<sup>48</sup> and Slade and Priebe<sup>5</sup> recommend borrowing on the methodologies of the social sciences and humanities. Speaking in part about the complex dilemmas facing the individual practitioner, Greenhalgh<sup>48</sup> points to the fact that our reliance on evidence-based medicine perpetuates the myth that we can reduce the uncertainties and ambiguities of medicine to simple questions about outcomes, interventions and populations. She describes this approach as reductionist, and advocates a combination of interdisciplinary research and an openness to new and innovative paradigms.

*"It is only by grappling with unfamiliar paradigms that the limitations of our own will become evident"* Greenhalgh<sup>48</sup>

Glasby and Beresford<sup>2</sup> drawing upon their experiences of approaching different journals for publication, point out that different academic

disciplines have divergent views about what constitutes valid research. In a similar vein, Webber and Carr<sup>49</sup> refer to social work knowledge as being derived from multiple sources: 'social theory, social research and the experiential knowledge of individuals, families, communities and human service organisations'. Perhaps more cross-disciplinary research would help to build bridges and broaden our understanding of what constitutes acceptable evidence. This may be part of the answer, and certainly it has the potential to engage with different sources of evidence.

### 3. Validating different sources of knowledge/evidence

Increasingly, service users and survivors are combining sources of knowledge in creative ways to produce a more comprehensive evidence base. Beresford<sup>35</sup> speaks of the need for a range of sources of knowledge – that a full spectrum of research approaches should be considered for inclusion in an understanding of evidence for policy and practice.

As an example, Rose et al<sup>50,28</sup> and Fleischmann<sup>51</sup> write about enabling service users to carry out, or become involved in carrying out, systematic reviews. Rose et al<sup>28,50</sup> report a systematic review of patients' perspectives on ECT, a review that was subsequently taken account of by NICE. Both describe a process that is more flexible than a conventional systematic review in the evidence they consider, including 'grey' literature and paying particular attention to reports authored by service users and research where service users' views have been obtained directly. They also seek out first-hand accounts of direct experience which they analyse as part of their review.

Glasby and Beresford<sup>2</sup> describe a review they carried out of hospital care, which included user-focused studies and qualitative research and highlighted issues of abuse and discrimination. They point out that, if the review had only included systematic reviews or RCTs, it would have found almost no evidence and would have missed significant issues of human rights in relation to quality of care. They ask the question:

*“What is more important – an academic commitment to a particular way of knowing and researching the world, or the alleged abuse, extreme boredom and poor quality care that some service users say they experience in mental health hospitals?”*  
Glasby and Beresford<sup>2</sup> p.278

## 4. Qualitative methods

There is something of a tradition for survivor researchers to adopt qualitative research methods because of the focus on hearing people's stories. Implicit in the requirement to hear and respect experiential knowledge is the use of, for example, unstructured or in-depth interviews, narrative research or focus groups. Service users 'bear witness' to each other's stories in what can be a powerful and empowering process.<sup>52,33</sup>

This goes some way towards ensuring that we hear the experiences and views of service users, and is certainly the approach that I have taken in the past.<sup>55,33</sup> However, qualitative methods alone may not be the answer. Used in the 'wrong' way, qualitative methods can be just as disempowering as any other research method. Church<sup>54</sup> challenges our use of narratives in qualitative research if we use and interpret them within existing paradigms. Costa et al<sup>55</sup> similarly voice a radical challenge to what they refer to as the 'pornographic' use of people's stories. Both are calling for service users and survivors to take back control of their/our stories and to make our own decisions about what our stories say, rather than falling in with the dominant paradigms of illness and recovery.

Jones et al<sup>37</sup>, in advocating capacity-building among survivor researchers, suggests that survivor researchers need to be skilled in quantitative methods as well as qualitative. They argue that the issue is not primarily about the methods but about the perspective or standpoint, and that a stronger user/survivor presence in quantitative research may be an effective way of infiltrating and influencing the complex power-knowledge relations of mental health research.



## 5. Collaborative research

Many service user/survivors and professional authors advocate taking a collaborative approach to research, thereby ensuring that different perspectives come together and make for a greater or more comprehensive whole.<sup>4,2,31,26</sup> Similarly, Evans et al<sup>46</sup> in developing an outcome measure for inpatient care, demonstrated that a participatory methodology could generate items prioritised by service users not included in traditional measures. (Examples were: safety and security issues, and items on diversity).

These examples and others may be genuinely collaborative and creative in ensuring that different perspectives are taken into account throughout the research process. Indeed, there is a vast literature on service user (or public) involvement in research going back over the last two decades.<sup>56,45</sup> However, collaborative approaches can operate by working within the existing research frameworks with clinical academics 'using' service user interviewers or researchers to gather the data and give their research more validity. Jones et al<sup>37</sup> and Russo<sup>39</sup> have highlighted the potential for participatory methods to perpetuate the dominance of the medical model by 'involving' service users in studies that do not challenge the existing paradigm. It is almost as if service user perspectives are sanitised or controlled, kept in their place.

## 6. User-controlled research

Many survivor researchers advocate user – or survivor-controlled research to extend and to build our collective experiential knowledge.<sup>57,39,26,36,58</sup> For Russo, survivor-controlled research in mental health constitutes a radical critique of both the biomedical model of madness and distress and the conventional understanding of research roles. Faulkner<sup>58</sup> in exploring several examples of user-controlled research, concluded that they examined themes and issues of concern to marginalised communities that would not have been researched by anyone else in any other way.

Community-owned research has been identified by Jones et al<sup>37</sup> as a key way forward. Community-owned research is research that is genuinely based in, and controlled by, the community, in this case, of mental health service users/survivors. Jones et al<sup>37</sup> argue for a return to the original concept of participatory action research (PAR) where research is integrated into the '*development and consciousness-raising activities of the community in its own efforts towards liberation*'.

In mental health service user/survivor research, they say, community-owned research needs to be aligned with the user/survivor movement's principles of autonomy, independence and self-determination. Only in this way can true alternatives to the mainstream mental health system and ways of understanding madness (sic) be explored. This approach suggests a return to the principles of emancipatory research as described by Beresford<sup>59</sup> and others, and is a means to ensure that research relevant to minority and marginalised communities is prioritised.

## 7. Supporting Academic User/Survivor Researchers

Another approach advocated by Jones et al<sup>37</sup> is to focus on supporting and capacity-building amongst academic service users and survivors: transforming academic research from within. This means not just training in research skills of all kinds, but supporting their potential to challenge attitudes within academic institutions and, crucially, to expand the nature of knowledge about mental health: perhaps a proliferation of departments of 'Mad Studies'<sup>60,61,62</sup> (see also: The Icarus Project: [www.theicarusproject.net/wiki/mad-studies](http://www.theicarusproject.net/wiki/mad-studies)).



# In summary...

Questioning the very nature of knowledge can make it feel as if the ground is shifting beneath your feet. Suddenly nothing is certain. How can we trust any research once we begin to unravel the assumptions, influences and biases inherent in its conduct? A reading of *Bad Pharma* by Ben Goldacre<sup>25</sup> is enough to make you never trust another drug again. However, many researchers would claim that it is only by asking these questions that we can truly understand our world. We need to acknowledge our personal perspectives or standpoints and use them to illuminate our understandings of the world.

There is powerful political resistance to viewing psychiatric patients as experts or as valid sources of evidence in their own right. Despite all the initiatives undertaken with and by service user/survivor researchers over the last few decades, the evidence hierarchy, which places the randomised controlled trial at the apex, remains. The knowledge and evidence produced by service users and survivors, whether as independent or community-based researchers or as collaborators, remains marginalised. There are instances of service user/survivor researchers' contributions being 'infantilised' or dismissed as irrational, anecdotal or biased.<sup>13,25</sup>

As I hope I have demonstrated in this paper, the randomised controlled trial is far from being the '*only gold that glitters*',<sup>5</sup> indeed, it is decidedly tarnished. It is time for all of us to develop and use a greater breadth of methods as befit the research questions, and to ensure that we draw upon a diverse range of sources of evidence. More importantly though, we need to stand alongside clinical academic researchers and bring our knowledge and skills to the table if we are to change the real experience of mental health services. I finish with a quotation from Mary O'Hagan, survivor activist from New Zealand, writing in the foreword to the book '*This is Survivor Research*'<sup>63</sup>:

***“Survivor research... challenges [the belief that madness is not a full human experience] in a myriad of ways – by its very existence, its curiosity and respect for subjectivity, its reluctance to distance the researcher from the research, its critique of knowledge, power, value-free research and the standard hierarchy of evidence, and its empowering methodologies. All these challenges, implicitly or explicitly, rest on the revolutionary idea that madness is a full human experience” (p.i)***

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