Chapter 17 Research in therapeutic practice settings: Ethical considerations

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The reciprocal relationship between research and practice is strongly emphasised in professional psychology and therapy training, particularly in courses where the scientist-practitioner model prevails. Yet, research and clinical practice skills are frequently addressed as if they are distinct. Research is typically viewed as important but as a hindrance in, therapeutic settings. Consequently, research skills are commonly seen by trainees and clinicians as an additional requirement, instead of a core skill. Post-qualification, political and service pressures often result in a de-emphasis on research activities, which can discourage research and narrowly define what is permissible, required, or deemed desirable. Whilst research in services can improve overall performance and practices (Mckeon et al., 2013), clinically-relevant research is increasingly viewed as only research which informs evidence-based practice (EBP). EBP is a contested area, including questions relating to what data is collected and how it is analysed and unsurprisingly, many clinicians hold negative views (Baker, McFall, & Shoham, 2008; Spring, 2007), as well as questioning how EBP can limit service user (SU) and clinician choice (Kerridge, 2010). See Chapter 18 for further discussion on EBP.

In this chapter, it is argued that research in therapeutic settings is essential and useful in generating relevant data to inform clinical practice, service development and health-related policy. Researchers do not need access to numerous resources, employ complex methodology, or recruit large sample sizes to conduct meaningful, high quality research with 'real' and immediate clinical implications. There are a range of avenues to conduct research in services and each pose their own practical, methodological and ethical challenges, some of which are addressed here before outlining an approach to ethical decision-making.

Defining research in therapeutic settings

Several activities in services involve information collection and it is important to distinguish whether data gathered falls under the umbrella of research, audit or service evaluation. The differences lie in the purpose and methods of data collection and the processes followed. Clinical records constitute data collection, but often are not anonymised and are subject to data protection. Intake information may be collated and the data anonymised – but this data

may be for monitoring service activities, demographics etc. Where data is gathered specifically for reviewing a particular aspect of the service, it may be considered an audit, or service evaluation. Where data is collected for addressing a particular question about the service, or a practice, or interventions used, this can be considered data for research.

The key characteristic of research is that procedures followed are in addition to, or different from, routine care; for example, random allocation or interviews with SUs. Research, will therefore involve administration of a Participant Information Sheet (PIS) outlining study details and consent-seeking procedures. Audit or service evaluation examines existing data collected as part of routine care, though may also involve questionnaire administration or interviews. Interviews can be controversial; one could propose that if the focus is on the experience of the care received then this could be framed as service evaluation. A clear articulation of the goals of the activity planned and proposed methods are crucial to ensure that ethical concerns are systematically addressed, preventing unethical data use.

Research in therapeutic settings often involves asking questions driven by the needs and goals of service users and providers, to identify areas for change in the type and frequency of care offered. Once research questions are generated, the research design best suited to answer those questions will require selection. Good practice (see Box 1) includes ensuring the research questions inform methodology rather than which type of evidence is viewed as most valid or rigorous. The multiple roles of the researcher and potentially conflicting agendas require careful consideration in terms of how participants are recruited, who collects data and possible adverse impacts on participants. Inclusion criteria should reflect the diversity of SUs referred to services and not be bound by linguistic barriers. In order to address the needs and goals of *all* SUs (including those from minority ethnic backgrounds and those whose first language may not be English) as closely as possible, SUs should be consulted, and the research may require interpreters and/or SUs. This can be a complex process; the challenge is to ensure that researchers work in partnership with SUs and/or interpreters (see Morrow, Ross, Grocott, & Bennett, 2010; Patel, 2003).

Box 1. Summary: Good practice in research in therapeutic settings
• Form research questions based on service user and provider needs

- Select the most appropriate design for the research question
- Address the role of practice-based evidence
- Recruit realistic sample sizes
- Consider dual roles of the researcher and participants
- Acknowledge and make transparent competing agendas (of the service, clinicians, researchers, SUs)
- Consult and collaborate with SUs in deciding what and how data is collected
- Ensure the inclusion criteria do not unfairly exclude particular groups
- Work in partnership with interpreters, where needed in research

Ethical considerations: Where do they begin?

Within the context of research, ethics have been described as *"moral principles specifically needed to guide scientific investigation"* (Thompson & Russo, 2012: 33). Yet ethical issues are pervasive and multifaceted; they are not always predictable nor can they be 'tackled' using universal protocols and general guiding principles. Profession-specific guidelines and the process of seeking ethical approval have led to an overly sanitised approach to research which disregards the numerous challenges and unique ethical considerations specific to who the research is with and where the research is conducted. Whilst useful, guidelines can be mistakenly treated as checklists, beyond which unique features of a clinical setting or research study are neglected. Further, the process of identifying and detailing the management of ethical issues, as if solely for the ethical approval process, can mask unexpected or unknown dilemmas that might arise. This also discourages and/or minimises the need for ongoing reflection and discussion of ethical considerations.

Traditionally, ethical concerns focus on the treatment of participants, researcher safety and the handling of data. However, there are a plethora of ethical challenges which require numerous, sometimes repeated and complex decision-making processes. Ethical considerations begin much earlier than procedural aspects of the study; they can start at the point of choosing or considering an area to be researched and the formulation of the research question. The researcher should ask a range of questions to determine what, why and the implications of designing a study in a particular area (Box 2).

Box 2. Choosing a research topic: Ethical considerations

- Is the topic an over-researched area?
- Who are the participants and their backgrounds (e.g. ethnicity, class) in the majority of those studies?
- Who or which research teams dominate in their contributions to the literature? How are they funded, by who and what are their research agendas?
- What topic areas/population groups are under-researched? Why might that be?
- How could your study contribute to this (or not)? Why design a study in this area?
- Who is asking for this study to be conducted? What are their priorities and why?
- What aspects of privilege and power would the proposed study potentially reinforce? How might a study be designed to offer an alternative perspective?
- Whose voice and agendas will be served by the findings? How might the findings be used/ misinterpreted, by who and with what possible impact and on whom?

Differing agendas of funders, services and researchers can create challenges. For instance, service commissioners might place an emphasis on certain outcomes and favour specific outcome measures, which clinicians or SUs might object or assign less weight to (e.g. symptom reduction versus SU goals). It is therefore vital that the researcher is able to acknowledge why the study is being conducted and form meaningful and relevant questions that do not simply satisfy particular stakeholders or generate data to support a set of pre-determined outcomes. Ultimately, the questions should fit as closely as possible to the objectives of the service and SU experience.

The research question is commonly viewed as the driver that informs all other decision-making processes in a linear fashion, though there is an important relationship between the research question and epistemology[1]. Specifically, the researcher's epistemological position informs the framing of the research question, whilst the research question is informed by the way a topic is researched and conceptualised in the field, dominated by a particular epistemological stance (e.g. positivist research seeking to establish specific relationships between certain symptoms or diagnoses and other factors). As the research question is a visible marker of the ethical positioning of the study, it demands careful construction and ethical scrutiny. The framing of a research question inevitably embeds particular assumptions

[1] Epistemology = the nature of knowledge, what claims can be made.

and the researcher should be aware of implicit assumptions to ensure consistency and coherency in subsequent stages. This includes examining the framework used to interrogate the literature; epistemological and ontological[2] positioning; methods employed; and data analysis. Ethics is a connecting strand, from selecting the topic area to how findings are used and should not be viewed simply as an attempt to satisfy reviewing bodies.

Task 1: Review the research question '*Has racism increased in healthcare settings in the United Kingdom following Brexit?*'

Consider the following:

- What assumptions are implicitly present? Does their presence matter and why?
- What needs to be made clear about the constructs used?
- How might racism be measured? Is it possible to measure? What does measurement imply?
- How might the question be reframed to avoid unwanted assumptions or implications of quantifying racism?

Research designs in the therapeutic context

A number of designs can be employed in the clinical context: small-N, which can include both quantitative and qualitative data; pure qualitative approaches; large-N designs, which rely on group comparisons. Each has advantages and disadvantages but importantly, all raise ethical questions.

Small-N

Narrative case studies, single-case and case-series experimental designs combine research and practice in an organic way. Ethically, these idiographic approaches are less problematic as the participant serves as their own control (i.e. an intervention does not need to be withheld from a control group). Instead of comparing data between participants, data is compared at different phases for the same participant – mapping individual change. Consequently, change does not need to be solely defined by service protocols or clinician expertise, but can be generated by the SU. Unlike tightly controlled large-N studies where exclusion criteria strip away the complexity and diversity of those referred to services, small-N approaches can be participant-focused and -led. Nonetheless, small-N studies are seen as more prone to bias and are less valued as evidence, in comparison to meta-analyses for example, where its purported value increases the likelihood of funding and publication,

[2] Ontological = the nature of 'reality'/being, what is there to know.

thereby perpetuating the privileging of more studies using these methods. Researchers have a responsibility to question how they can engage with research to shift this restrictive exertion of scientific power, embedded in the hierarchy of evidence, which has been criticised, for example, on its failure to serve the needs and realities of public policy (Parkhurst & Abeysinghe, 2016). Research designed and carried out by clinicians in *real* therapeutic settings is likely more valuable and relevant to SUs, professionals and services. Small-N designs link more closely to the clinical needs of the individual rather than epidemiological factors that form the basis of larger studies; and they allow practice-based evidence as one way of using a bottom-up approach to inform policy.

The publication of small-N studies is on the rise, perhaps a result of attempts to increase credibility with the introduction of randomisation (Kratochwill & Levin, 2010) and the employment of various statistical analyses, including effect size. Despite an increase in statistical options, results can differ based on the technique used (Parker & Brossart, 2003), and so caution is advised and a clear rationale should be provided for the chosen analysis (e.g. avoid selecting techniques that simply support research questions). Ethical dilemmas continue to emerge at the analysis stage, for example, as significant findings are more likely to be published, non-significant findings are generally dismissed; however, both could lead to new questions and lines of enquiry.

Many criticisms are directed at traditional case studies, but in an attempt to reduce researcher bias, increase external validity and link change to therapy, there is a drive for systematic approaches that collect quantitative data and include multiple assessment points and cases (Elliott, 2002). This may create problems for studies using therapies with less emphasis on observable phenomena and where using quantitative measurement to map onto constructs of interest is not possible. Unfortunately, in order for small-N designs to be regarded as credible and rigorous they have increasingly adopted qualities of designs more common to cohort studies and RCTs.

Ethical considerations in small-N designs are complex (see Box 3). For example, with respect to informed consent and confidentiality, using data for research purposes without the SU's permission could be seen as unethical. Others might advocate that clinicians are continually formulating and testing hypotheses during their clinical work, thus recording data does not

interfere with this process, and consequently does not require SU consent. Small-N approaches involve more identifiable information due to the nature and amount of data gathered and it can be easier to identify services – making it imperative to consider how to ensure informed consent and confidentiality, and monitor researcher bias, which can influence the research agenda.

Box 3. Ethical considerations in small-N designs

- How can the influence of the research agenda of the clinician/researcher be reduced?
- What issues arise with using data retrospectively once the intervention 'success' is known?
- Is it always unethical to disseminate/publish data from small-N studies without SU consent? When might consent not be an issue?
- Can removing personally identifiable information always ensure confidentiality?
- What issues might arise as a result of excessively removing identifying information?
- How could the misuse of power by the clinician/researcher be monitored?
- How can ethical considerations be addressed in reporting (e.g. conferences) or publishing findings from small-N studies?

Qualitative studies

Similar to small-N, qualitative studies which are smaller in scale might be better placed to address service user and provider issues (Harper & Warner, 1993). The focus on context, meaning and experience may allow SU concerns and goals to emerge more readily, requiring the researcher to articulate questions which elicit information that do not simply support existing frameworks or ideas, and to genuinely listen to participants. However, qualitative methods should not be chosen based on the misconception that they are ethically superior. Hammersley (1999, p.18) argues that qualitative *"ethicism*" is problematic as it may lead to a lack of engagement with complex moral dilemmas regardless of the methodology adopted. In fact, due to the increased amount and type of interaction between researcher and participant in qualitative methods, some researchers argue that these approaches raise additional ethical issues (Brinkmann & Kvale, 2008). Researcher reflexivity and attention to the researcher's own personal values, social position and background (and biases) are

essential to ethical considerations; though this could be said of all research designs. The impact of questioning participants from the researcher's own position requires reflection and the focus should not be restricted to differences between researcher and participant, but also on the consequences of assuming sameness.

Large-N

Large-N studies are more resource-intensive and in therapeutic settings typically involve assessing the effectiveness of an intervention. The way in which an intervention is evaluated has implications for its applicability to those accessing services. Randomised control trials (RCTs) positioned at the higher end of the hierarchy of evidence, assess the ability to produce the desired outcome under tightly controlled, stable circumstances. In contrast, effectiveness trials assess the effect under 'real world' service settings. RCTs are viewed as the gold standard of EBP regardless of significant criticism in terms of their design and usefulness. Cartwright (2007) questions whether it is possible to have a universal 'best method' and concludes that it is not, and instead selection should be study dependent. The endeavour of RCTs to achieve high internal validity has come at a cost to external validity (Cartwright, 2010) and their promotion has led to a divide between research and practice (Carey et al., 2017). Hence, conducting RCTs requires careful consideration to ensure that findings are meaningful at multiple levels (e.g. SU, clinician and service).

Overall, RCTs assume causality based on statistical associations, but do not answer questions regarding mechanisms of change. Therapeutic interventions involve numerous interrelated technical and relational variables and accordingly, Elliott (2010) argues that 'true' EBP should involve multiple lines of change process evidence (how and why change occurs). EBP reliant on RCTs has been critiqued for prioritising the needs and values of funders and service providers, whilst limiting SU choice (Kerridge, 2010). RCTs determine the nature and frequency of care offered by services, and SUs who do not match subsequent guideline expectations are viewed as drop-outs or non-engagers (Carey, 2018). Researchers need to ask themselves how research can continue to be viewed as rigorous and valuable *and* be led by SU perspectives. Outcome measures typically used in these studies focus on symptom reduction and neglect other forms of change, which are potentially problematic as SUs may continue to score within clinical ranges but report improved quality of life, thereby missing

the perspective of the SU. Participatory Action Research aims for equal involvement from both researchers and participants using an iterative process and offers a compelling alternative. As an approach it acknowledges that participants are not passive in the research process and actively involves them (Baum, MacDougall, & Smith, 2006). However, it is not a panacea and does not *fit* all epistemological positions and methodologies.

Practically, RCTs are costly and time-consuming and they cannot easily be integrated into a clinician's daily work, which brings into question who carries out these studies, who funds them and with what agenda. There is an assumption that treatment effects will be the same across different contexts and despite issues with external validity the findings of RCTs continue to inform policy. For example, as intervention components individually and combined largely remain unstudied, there is a lack of clarity about how these factors interact with context (Bonell, Fletcher, Morton, Lorenc, & Moore, 2012) and therefore, how they can be replicated. Bonell et al. (2012) argue that a more meaningful question than the traditional 'what works for whom' is asking *what works for whom and under what circumstances?* This highlights the need for further effectiveness studies, which can be more readily carried out within services and anchored in terms of geographical location and demographic characteristics of the local population.

Data collection: Challenges to ethical practice

Data collection in services usually takes the form of self-report, ranging from structured questionnaires to unstructured interviews. An unavoidable ethical tension for clinicians conducting research in such settings is the duality of roles (clinician-researcher). Juggling too many roles can impact upon the ability to make ethical decisions (Seider, Davis, & Gardner, 2007) and competing agendas and participant expectations can lead to role conflict (Yanos & Ziedonis, 2006). For clinician-researchers conducting research in their own service, organisational and clinical agendas or responsibilities may compete with the research agenda. If the participant is a SU (SU-participant), they may struggle to distinguish between the roles and expect clinical input (Holloway & Wheeler, 1995). Furthermore, what one might do in therapy is not what is expected as a researcher; the roles are governed by different obligations. The goal of a clinician is to provide client-centred care and ensure wellbeing – there is flexibility in terms of how this may be achieved. Within research, the rights, safety

and wellbeing of participants are given a significant platform, but the researcher has to adhere to specific and often standardised procedures to ensure 'quality' of data. It is, therefore, key that the clinician-researcher make clear their role within each interaction and clarify the parameters of how information communicated by the SU can be responded to. It is recommended that researchers who have an existing therapeutic relationship with a participant avoid direct contact, such as recruiting or interviewing (Sales & Folkman, 2000). Nevertheless, even the association of a clinician name with a study has implications, as SUs trust in clinicians can increase the likelihood of them opting into research (Kaminsky, Roberts, & Brody, 2003).

A systematic review of clinician-researcher dual role experiences in health research highlighted the vital role of supervision (Hay-Smith, Brown, Anderson, & Treharne, 2016). Others have argued for an integration of roles to form a 'coherent moral identity' as a way to minimise unethical practices and protect participants (Miller, Rosenstein, & DeRenzo, 1998). In fact, some suggest the aim should be to develop internal models driven by underlying principles which direct one's work, to enable clinician-researchers to learn how to prioritise and resolve conflicts (Yanos & Ziedonis, 2006). Additionally, professional training courses need to dedicate reflective spaces to explore these ethical tensions.

Interviews

Interviews with SUs, carers or professionals may take the form of individual interviews and/or focus groups. Interviews allow participants to direct the conversation to some extent, with less of a researcher framework imposed than structured methods. Clinical skills in being curious, listening actively and empathically are advantageous here, although clinician-researchers may unknowingly misuse these skills, for example, where participants communicate information that they may not wish to share (Brinkmann & Kvale, 2008).

Depending on the topic area and sample, considerations should be given to where interviews are conducted and by whom (e.g. gender, ethnicity, role). The researcher should be aware of their own position and the values that they bring to the interaction, in addition to the power differential between researcher and participant. Interviews can be emotive, and the participant should not feel obliged to continue (e.g. for fear of upsetting the researcher/clinician, fear of withdrawal of service etc.). Unexpected content may emerge

during the interview and consent to use in the research should be revisited at the end of the interview. Similar to small-N approaches, the nature of data collection may lead to participants being more identifiable, and extra precautions need to be used, such as, the use of pseudonyms, changing or removing names and/or places. Confidentiality and anonymity require particular attention when conducting focus groups; there needs to be an agreement that members do not discuss information following the group or share information with others. This can be more difficult to guarantee, which points to the need to justify why relevant data can only be obtained in group interaction.

Questionnaires

Questionnaire data can be collected face-to-face (subject to the aforementioned ethical dilemmas) or electronically. The latter may reduce some of the issues raised, but questions emerge regarding how to: ensure valid consent; assess and manage the emotional impact of participation; sufficiency of online debriefing (British Psychological Society, 2017). In terms of data security, it is paramount that secure platforms are used to collect data and that storage is on organisation, password protected, computer files rather than cloud services.

Task 2: How might a clinician-researcher explain their role and the parameters of their responsibilities to a SU-participant?

- Will this be a one-off explanation?
- Which aspects require emphasis?
- How might one ensure that different interactions do not become confusing for the SU-participant?
- How can the clinician-researcher remain clear about their role within a given interaction?

Ethical questioning and decision-making throughout the research process

Through a series of illustrative, not exhaustive questions (see Box 4) this section addresses aspects commonly scrutinised by ethics committees, and more subtle dilemmas frequently overlooked. However, it is not possible to predict all possible ethical dilemmas a study may pose and unexpected issues will undoubtedly arise.

Ethical decision-making can be more straightforward for certain aspects due to legal frameworks, such as the General Data Protection Regulation (GDPR; *Data Protection Act 2018* [c. 12]). This new stringent European legislation is likely to ensure increased accountability, particularly the collection, handling and storage of identifiable data, essentially to reduce data breaches. Nevertheless, all decision-making processes should be viewed as equally important in terms of ethical practice, despite less obvious or explicit penalties. Furthermore, even when there are legal obligations as with the GDPR, the practical implications are debatable and will require ongoing discussion by all researchers.

Box 4. Ethical considerations for research in therapeutic settings	
Stage	**Questions to ask**
Advertisement	How are participants made aware of the study (e.g. posters/leaflets in waiting areas, staff circulating PIS – direct requests can exert pressure on SUs)? Whose name is associated with the project (clinician trust can influence decisions to participate)? How is the study 'sold' (e.g. will help other SUs, quicker access to help etc. – implications of such statements)?
Recruitment	Are staff involved in the SU's care inviting participants? How do staff decide who to invite and what are their assumptions, expectations and biases? Is an external researcher involved in recruitment? What challenges might this overcome and/or raise? Has it been made clear that a decision not to participate will not affect care the SU continues to receive from the service? Has a time pressure to opt-in been communicated? What other options are available? Has the SU's motivation for participation been explored?
Inclusion/exclusion criteria	Are the selected criteria all necessary?

	Will the criteria exclude particular groups – who is explicitly, and implicitly excluded and why? What are the implications for the study and findings? How might this (e.g. those who do not speak English as a first language) be overcome? Does the criteria sufficiently represent those referred to the service or the target group? Will the criteria lead to particular findings being supported (i.e. reinforce existing outcomes)?
Information sheet	Are there opportunities to access the information via other means (e.g. brail, audio, languages other than English etc.)? Will deception be used? Is this necessary? Have the consequences been considered? Has information regarding supporting agencies been provided in case of withdrawal?
Consent	Does 'capacity' need attending to? In what way? Is parental/guardian consent required? Will consent be revisited as an ongoing process?
Demographic information	Is unnecessary information being collected (i.e. not relevant to answer the research question/s)? How is information being collected? What are the implications (e.g. closed categories such as, male or female, what might be participants' perception of an 'other' option, could a free text box be used, what challenges might it pose)?
Data collection	Who is collecting data? What agendas do they bring? How is data being collected (e.g. interpreters) and where? Is only necessary information being collected? If electronic data collection, are secure platforms being used?
Right to withdraw	Has it been made clear that participants are free to withdraw at any time (even after an interview) without the need to provide a reason and with no negative repercussions? How could the obligation to continue in fear of disappointing the referring clinician/researcher be reduced?

Data storage and security	Has all identifying information been removed? Has identifying information which needs to be kept been stored separately to data and contact details? How long will data be kept for (i.e. data should not be kept for longer than necessary, typically 3-5 years)? Has identifying information been shared with anyone outside the research team? Where and how has data been stored (e.g. appropriately encrypted, password protected files, separate networks that are not shared, not on cloud services)? If in locked cabinets, who has access? What issues might arise related to location of data storage with online questionnaires (i.e. UK versus USA-based)?
Withdrawal of data post-participation	Is there an option to withdraw data post-participation? How will this be managed? What if participation was anonymous?
Debriefing	If deception was involved, has the necessary information been communicated and the impact of withholding this information assessed? Have participants been appropriately signposted to supporting agencies?
Compensation	Are financial incentives being provided? If yes, in what form, why and with what implications?
Dissemination	It can be viewed unethical not to disseminate – who would benefit from learning about the study (other than academic/professional audiences)? Who has been involved and at what stage (e.g. interpreters, SUs, management)? Has their input been acknowledged? How? Is SU involvement tokenistic or genuinely ensures co-production (e.g. co-authorship)? Will findings be shared with participants? If not, why? Has the impact of seeing/hearing the results been considered? How can the misuse of findings be prevented?

Conclusion

A focus on EBP has led to a misconception that research in therapeutic settings should take the form of large, tightly controlled, comparison studies. In reality, there are a range of clinically-relevant questions that demand a range of methodologies, based on questions and priorities of SUs and services. Conducting research in services can be challenging and generate a minefield of ethical issues, due to political and professional pressures, multiple roles and agendas, the diversity of SUs accessing services and the operation of power (in research frameworks, service-level systems and in the SU/participant/researcher/clinician relationships). To carry out research that is as closely aligned to the concerns and experiences of SUs, and appropriately generalisable, research in the therapeutic context should involve working in partnership with SUs – it cannot be solely steered by policy makers, funders and service providers. Numerous systemic and economic barriers will need to be navigated to conduct ethical research, which requires ongoing questioning, discussion, and supervision.

Reflective questions

1. How might a researcher design a study led by SU perspectives whilst managing conflicting agendas?

2. In what circumstances might a researcher choose to conduct a study where findings could be used to support ethically questionable agendas?

3. How might a researcher reduce the power differential in the researcher-participant relationship?

4. What should a researcher do if a participant discloses information that has negative implications in relation to their clinical care?

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