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Title: Developing a research framework to inform an evidence base for person-centered medicine: Keeping the person at the centre.

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Abstract:

Person-centered medicine exists at the intersect of science and humanism and has the dual goals of relational and evidence-based practice. In the operationalization of humanistic medicine then, the development of a sympathetic and facilitative research framework is a priority. The *person-centric research framework* is proffered as one such model and will be described in this paper with a view to eliciting discussion about the essential qualities of a person-centered approach to evidence generation. This framework has been emergent from the clinical practice of the author, and builds upon other pioneering work in this field. It is operationalized as a practitioner-informed philosophy of the conceptualisation, practice and interpretation of research.

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Evidence-based practice is a prerequisite for all medical and allied health disciplines. The person-centered community has to date, spoken to this requirement in one of two ways [4]: (i) establishing the efficacy and equivalence of person-centered approaches by adopting comparable positivistic research methodologies [1,2]; and (ii) using non-traditional methodologies, largely qualitative, in a bid to move beyond the question of equivalence and toward an exploration of exactly what elements or qualities of the person-centered approach are effective in supporting positive patient outcomes [3]. Both approaches have made substantial contributions to the evidence-base - the former approach affords credibility beyond the person-centered community while the latter generally feels more aligned with the philosophy of person-centered practice. However, both approaches are somewhat slavish in their commitment to one particular type of research methodology, each with their own limitations. Ideally, choice of research methodology should follow from the identification of a question and a philosophically driven consideration of how best to answer that question. At this juncture it seems apposite to reflect on what research values might support or undermine an evidence-base for person-centered practice with a view to developing a philosophical or values-driven model for person-centered research. The current paper acknowledges the genesis of person-centered research as belonging with Rogers and aims to present a conceptual and pragmatic synthesis of the subsequent history of person-centered research to afford a sound base on which this conversation can progress.

A historical perspective

In medical and allied health spheres, the development of an evidence-base currently relies heavily on the adoption of positivistic scientific methods from the physical sciences in an effort to remove human error variance from the equation. Removing human error variance however, poses a problem for practitioners in the human sciences as it inherently distances research from the daily realities of clinical practice [3]. There is often a disjuncture, for example, between treatment studies using methodologies such as randomised control trials (RCT's) (usually considered the gold standard research methodology) and the practitioner's experience. RCTs typically involve the use of participant selection based on membership of a singular diagnostic category despite it being rare for a clinician to come across individuals who can be so neatly categorised [5,6]. Moreover, in achieving the controlled conditions central to the RCTs notion of internal validity, there is also a large range of other participant exclusion criteria that eliminate on average two-thirds of clients who might attend for treatment [6]. One example of this, the routine exclusion of suicidal clients in RCT treatment for depression, clearly illustrates a fundamental challenge to the external validity of the findings [7].

Treatment studies using RCTs also almost unanimously make assumptions about the supremacy of treatment technique over therapeutic relationship when selecting the few outcome measures on which they rely. In the context of psychological treatment there is a focus on whether symptom reduction can be attributed to, for example, cognitive-behavioural or psychodynamic intervention approaches. This is despite replicated findings from meta-analytic studies confirming that such techniques accounts for roughly only 15% of the outcome variance [8,9]. While other factors have been found to be reliably more potent in treatment outcome few bother to assess extra-therapeutic or client factors (such as the use of self help, quality of social support, spontaneous remission or client motivation) which account for 40% of outcome

variance in treatment; expectancy and placebo effects which account for 15%; or therapist attributes (such as competence and interpersonal style), facilitative conditions (including empathy, warmth, positive regard) or the therapist-client relationship which account for 30% of outcome variance [10, 11, 12, 13]. Obviously many of these dominant yet 'invisible' elements are the realm of person-centered practice and so are even more critical in research designed to inform such practice.

Bergin argues for an expansion beyond traditional methodologies, noting that a "person is more than a collection of variables", that "a change process cannot be construed as a linear form of temporal and impetus causality" (p.85)[10]. Kippax & Stephenson also critiqued the "fetishised" (p.361) commitment to the randomised controlled trial (RCT) as the single gold standard methodology [14]. When charged by the American Psychological Association (APA) with the task of evaluating the state of psychotherapeutic research, Norcross also observed that the EST lists were "oddly person-less" (p.2) and that "most practice guidelines depict disembodied therapists performing procedures on Axis 1 disorders [15]. This stands in marked contrast to the clinician's experience of psychotherapy as an intensely interpersonal and deeply emotional experience" (p.2).

In sum, medical and allied health practitioners have additional challenges in the 'doing' of practice-related science compared to their counterparts in the physical sciences, due to the complexities of human experience which is the substantive focus of our study. In the human sciences there is an absence of the external objective locus available in the purely physical sciences. Thus, research findings emanating from traditional reductionistic methods are often fatally compromised for application and cannot provide a credible evidence-base for our practice. It is the thesis of this paper that in the same way that person-centered philosophy enriches our client practice, so it can enrich and define our research practice.

The practitioner's eye: A Person-Centric Research Framework

When we hold our research lens to the person-centered practitioner's eye, we are afforded the opportunity to re-connect with the object of our studies, that is, we hold the *person* at the centre of our research thinking. There are several core elements of person-centered philosophy and practice that are potentially powerfully translatable into research practice at all levels, from framing relevant questions, through choice of measures, to selecting methodologies and identifying sympathetic data analytic techniques. These elements are distilled in the *Person-Centric Research Framework* in figure 1, and are discussed below.

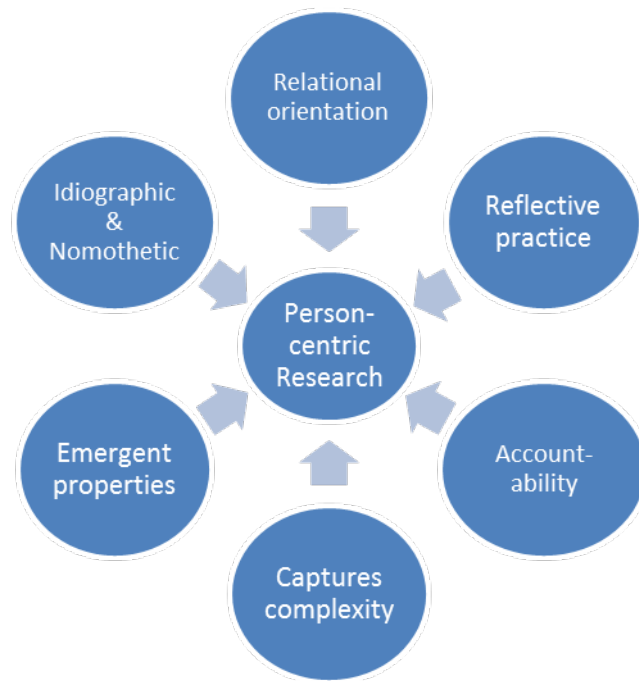


Figure 1: Person-centric Research Framework

Relational orientation: The perspective of the humanistic practitioner is critically brought to the table by attending to the relational qualities of the research process, preferring a collaborative form of relationship with participants than one based on expertise or researcher acting upon a subject. From the point of conceptualisation of a research project, systemic and relational thinking is prioritised in the formulation of questions, the selection of methodologies and the implementation of experimental intervention programs. Prioritised is the participation of co-researchers [16] or key informants [17] whom we take to include the practitioners and clients directly involved in the trial as well as service providers, potential clients in the community, and related researchers. Stakeholder comment can helpfully strengthen research design by evaluating the realism of questions identified, the relevance of the measures selected and the responsiveness of methods used to capture the likely *range* of responses to treatment. Service providers and clients can often highlight ethical dilemmas as well as pragmatic considerations in treatment design. As emphasised in the qualitative research tradition, triangulation of these different contextually embedded perspectives can add weight (or doubt) to the conclusions drawn [17,16].

Reflective practice: Gilbourne has suggested that reflections on practice, while not widely accepted in publications, are often “fine moments. They serve to bring the ...author into focus... and offer insights into a reflective practitioner facing up to the tensions between theory-driven and reality-driven practice” (p.212)[18]. He also suggests that “the *doing* of reflection needs to be matched with a willingness to share the end product” (p.198) [19]. This framework therefore values the perspective offered by the participant-researcher, including the intellectual and personal contribution afforded by *not* attempting to only consider things solely from an ‘objective’ stance.

Patton argued that the relationship of the researcher to the data is an important and relevant part of drawing enriched meaning from findings [16]. This reflective practitioner contribution affords micro and macro analysis of the research process and of treatment progress

and often provides critical insights that save an evaluative process from challenges to contextual validity. Sometimes this is in the form of illuminating notable non-occurrences. What is absent or not captured by traditional measures, yet is apparent to an experienced clinician, is often as important as what we see [17].

The impact of a participant observer on eliciting responses within his or her frame of reference must, however, be carefully considered and their role transparently described for others to evaluate [20, 21, 22, 23]. Extended participant observation provides an obvious and valuable opportunity for thick description [16] but also, though less considered in the literature, for curiosity-driven intrusiveness and hence, for compromise to pre-existing relationships between researcher and participants [24]. Patton advocates negotiating the degree of participation that will yield the most meaningful data [16]. More importantly perhaps is the criterion of *ethically supportable*, meaningful data.

Accountability: This issue perhaps speaks most directly to why practitioners need to be involved in research at all. We have a commitment to being sure that in our practice we do no harm. Moreover, that we are guided by information (data) about the therapeutic options open to our clients, and that such information is gathered in a contextually relevant and clinically meaningful way, rather than relying on non-practitioner researchers to understand the myriad nuances and layers of therapeutic practice when designing efficacy trials.

Accountability needs to be translated into methodological choices such as the type of data collection to be undertaken. For example, in studies requiring interviewing, there are closer synergies between therapeutic practice and hermeneutic or phenomenological interviewing techniques as opposed to the more reductionistic structured or semi-structured interview formats. In data analysis, rigour is equally important when using statistical techniques or qualitative and descriptive means of analysis. Even in the most successful intervention, predictive measures will result in some false positive and some false negatives and we need to be mindful of the sensitivity and specificity of the measures we use. In the context of therapeutic decision making, understanding the web of client characteristics that differentiates the success stories from the failures is critical, not a secondary issue to be overlooked in the joy of a large statistically significant finding or a robust structural equation model.

In sum, we need to be as interested in what went wrong and what *doesn't* work as in what does. Publishing conversations about treatments that did not work is critical, as is reporting what happened to treatment drop-outs, or at the very least sharing these conversations openly with other practitioners. In doing so, we remain keenly focussed on the faces of our clients when interpreting research data. As Gendlin notes, clinical research is often guilty of verification without exploration [25].

This careful collection and processing of data also speaks to the next issue, the importance of capturing complexity in our research.

Capturing complexity: In the Rogerian tradition, our research can be enriched when underpinned by a view of human nature is that of infinitely complex individuals embedded in a complex series of relationships and experiences which moderate their various experiences of life [26,27]. The person-centred notion of life as an endless journey of self-actualisation and personal unfolding changes what we measure and how we assess change. There is a mindfulness that felt change is sometimes evident in symptom change, sometimes in broader behavioural change, sometimes in changes in belief or emotional register, and sometimes in much more subtle ways.

Changes in knowledge can also precede behavioural change. Sometimes change is a transformative moment and other times a slow gradual movement or a ripple effect from a single apparently unrelated event. Many of these changes are hard to spot when assessed by a snapshot moment using a few psychometric tools [28]. Considering a range of these change processes in a single study is a practical challenge but makes for a richer potential for understanding our clients' experience and for more robust theoretical arguments [3].

Looking for singular, linear, unitary relationships is usually inadequate in psychotherapeutic practice and research [10, 3]. A mixed methods approach offers a rich alternative [29,30]. Psychotherapeutic research is at its most robust when it draws upon multiple measures including both qualitative and quantitative sources and includes different data collection methods such as interviews and behavioural observation to supplement self-report questionnaires [29]. Distal and proximal outcome measurement can similarly afford different perspectives on each participant's progress. Data analysis then must also be adequate for capturing within case and between case stories, and consideration must be given to configural relationships between variables. Drawing together this network of data is challenging.

Emphasising thick description over reductionism and highlighting the importance of being expansive at particular moments in the history of understanding a new phenomenon is important, rather than aiming for premature synthesis in an effort to conform to the publication requirements of experimental journals [31].

Honouring the person in the research equation is also sometimes best served by considering triangulation as an alternative to a control group comparison when attempting to establish the validity and reliability of treatment findings [16]. The underlying principle of planned triangulation is that converging evidence from considered, multiple and heterogeneous sources is more persuasive in the investigation of complex, socially embedded phenomena, than a single, necessarily imperfect attempt at measurement or the opportunistic meta-analysis of unrelated studies with incompatible or ill-considered flaws. Planned triangulation can build on the strengths of each type of data collection and minimize the weaknesses, while evaluating how different perspectives resonate with one another. As in clinical practice, triangulation of multiple sources of data, multiple types of data and multiple measures across time can provide strong evidence of convergence (or divergence) of findings lending robustness to conclusions [3,16].

Traditionally, research progresses by a sequence of studies, each examining the 'gaps' from previous studies. The mixed methods approach attempts to take a more holistic perspective within each study, gaining the advantage of thorough exploration of a question in several different ways, critically, with the same participant group, making results more directly comparable. Kazdin also talks about another particularly important form of triangulation in psychotherapeutic research, which also speaks to our ethical commitment to be as non-invasive as possible in people's lives. Specifically, he emphasizes the potential in knowing about the history of a disorder or presenting issue as a way of assessing causality of change instead of using control groups [32]. Using published norms on a particular measure as a point of reference for comparing client change can be a strong and less invasive option than having a control group. Constantly thinking of the impact of our studies on the participants is a critical element of this approach.

Berkowitz points out that 'good qualitative analysis is both systematic and intensely disciplined' and coalesces around consideration of the following questions: What specific patterns or themes emerge in response to specific prompts? How do these illuminate the broader questions of the study? Are there deviations and can they be explained? What interesting stories

emerge? How do they illuminate the broader questions? Do any of these findings suggest that additional data need to be collected? Do these findings corroborate any other findings? If not, what accounts for the discrepancy? [33]

Adopting ‘safeguards against self-delusion’ can add rigour in data analysis by extending regular notions of reliability and validity of findings (p.265)[6][34]. Specifically:

1. Evidence is considered with an eye to suggestions of convergence, relatedness *and* divergence. In so doing we need to check for outliers or extreme cases as opportunities for further elaboration or verification. Similarly we need to follow-up surprises.
2. The frequency and intensity with which issues are raised is considered as well as the frequency and intensity of response.
3. Emergent conclusions are drawn and tested for validity by way of sturdiness (i.e they are able to withstand alternate explanation), plausibility (i.e. the argument is credible) and confirmability (i.e. the finding is defensible).
4. Assumptions of the study are addressed so as to be in a firm conclusion drawing position
5. Hard conclusions are differentiated from more speculative conclusions.
6. Limitations, both methodological and conceptual, are discussed.

Careful consideration of optimal forms of data presentation is also integral in effectively illuminating complexity. In addition to traditional statistical tables and graphs, data display can variously take the form of an extended piece of text, diagrams and flow charts that provide a new way of thinking about the data. Flow charts often display critical paths, decision points and supporting evidence. Data display for intra-case analysis is considered as potentially powerful as cross-case analysis [29].

In taking these extra steps to appreciate the complexity of each individual participant’s results, we honour our clients and avoid premature foreclosure on understanding his or her experience.

Emergent Process: The research process can be viewed in much in the same way as practitioners view treatment - as an unfolding process involving iterative reflection and action. The first principle of the mixed method approach is that data consideration and analysis ought also be an iterative process where the findings from one element of the study should feed back into, and shine new light upon, the findings of previous parts of the study, resulting in confirmational support, further enrichment of our understanding of a particular issue, or the highlighting of a conflict that needs resolution for the research to progress [35,34].

This approach is consistent with mixed methodology frameworks such as Developmental Intervention Research [36] and Action Research [37]. This stance also points us to the importance of considering both formative and summative evaluation of our interventions [38]. It encourages us to consider what our data are telling us about how our intervention is working as it unfolds rather than waiting until the program is complete and reflecting posthoc on problems that have emerged. This allows us to uphold our ethical commitment to our clients. For example, when non-attendance becomes an issue, trying to assess what is contributing to that non-attendance may rectify the problem in a timely fashion rather than just making for a larger drop-out statistics in our research findings. Both inductive and deductive development is considered in this research process – an eye is kept to surprises as well as testing out hypotheses.

Idiographic & Nomothetic: Part of the person-centered commitment to capturing complexity lies in considering the optimal level of explanation and exploration in an investigation such that the person is kept clearly in view. In sum, idiographic and nomothetic types of analysis are of interest and can feed into an iterative investigative process rather than the sequential stage process traditionally associated with programmatic, particularly reductionistic, research [34]. Typically in psychology we focus on the nomothetic level of explanation – we consider differences at the level of groups. However, nomothetic techniques can “clarify by abstracting the most important bits of information” but also “obfuscate by submerging into averages individual differences that are vital to the understanding of the phenomena under investigation” (p.271)[39]. Idiographic approaches on the other hand, see the person as a whole but may focus in on a case that turns out to be extremely idiosyncratic. These case studies can sometimes be illustrative (eg a serendipitous, critical incident case study), sometimes exploratory (testing out key parameters of a tentative model) but can also be used cumulatively [40, 34]. Lamiell introduced this cumulative use of case studies as the idiographic approach which involves looking for patterns across individual profiles gleaned from idiographic measures and methods [41]. It is a bridge between these two approaches. The combination of these complementary approaches has the potential to result in a process of active theoretical evolution. Each method provided confirmational opportunities for the other but also, through a process of reconciliation of each level of observation, suggests new questions that would not have been elicited from either level of explanation independently [42, 43].

Valuing the contribution of case studies also alerts us to the importance of considering both statistical and clinical significance when evaluating change. While statistical significance has a long history, an appreciation of the impact of change in each individual’s life is less common. Clinical significance may be evaluated by considering whether a participant’s score on a key measure has moved from a clinical to non-clinical range of symptoms. Clinical significance may also be captured in statements made in interview that suggest a transformative experience even in the absence of significant changes on standardised measures of symptomatology. As discussed earlier, change is a complex process that can take many forms and idiographic considerations of change processes are the bedrock of counselling practice.

Beyond treatment studies

Each of these foci in the *Person-Centric Research Framework*, can help guide researchers to ask questions that extend in their relevance beyond the treatment studies discussed above. These research values are equally applicable to large-scale studies investigating myriad features of human development, and causes of illness and injury. Increasingly we understand that these studies, depend for their relevance, on contextual validity. A case study is presented here to further illuminate the point that this is a philosophy, a way of approaching research, rather than a methodology suitable to one kind of research.

One of the primary areas of research productivity of our team is paediatric neuroscience – a field governed by a very traditional research framework. Our current work involves investigating the neurodevelopmental sequelae of premature birth, chronic illness (Type 1 Diabetes Mellitus) and injury. Our clients are children of school age and their families. Over the past 18 years, thinking along person-centered lines has profoundly changed our practice in exploring the many trajectories of academic, social and mental health development. It has changed the questions we ask to reflect a more ‘whole of child’ philosophy; resulted in an

expansion to our team to be more interdisciplinary so that we can better consider the complexities of development in an integrated way; led to innovation in data collection methodology built around an innovative holiday activity format experienced as fun and games by child participants rather than as tedious testing (this is particularly important for our clients who have often experienced considerable medical intervention in their short lives); and changed our data analytic approach to include interest in individual cases as well as group differences. We are also more interested in exploring the child's experience of their academic, health or mental health difficulties as well as the experience of their parent and family as a way of contextualising our data. So, we still collect 'hard' measures such as event-related potentials (ERP's), MRI data, psychometric measures of development and a range of computer based assessment measures. We still use positivistic methods in addition to qualitative methods, we are still utilising a randomised control trial approach in our intervention trials. What is different is that the process, purpose and practice of these methodologies are informed by the values of person-centered practice. This makes all the difference to how we engage with our 'participant clients', collect our data, illuminate our data, interpret our work and how readily it can be translated into practice.

Summary

The intention of this paper is to present a fledgling framework for person-centered research and in doing so, to invite discussion about the role, breadth and practice of research in person-centered medicine. As person-centered practitioner-researchers we have a unique potential to offer - our commitment to keeping the *person* clearly at the centre of our thinking helps us illuminate a human axis around which the research kaleidoscope can turn.

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