Clinical outcomes of staff training in positive behavioural support to reduce challenging behaviour in adults with intellectual disability: Further thoughts on intervention, implementation and interpretation

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Abstract

Hassiotis et al (2018a, b) recently reported on a trial of the provision a short form of PBS training to staff working in National Health Service teams in England which reported no beneficial clinical effects from the intervention. In doing so, they acknowledged a number of factors that may have impacted on the outcomes. This paper is written by the trainers who delivered the intervention in the study and offers additional thoughts on the implementational issues with the research and the validity of its results. Its aim is to supplement the principal study reports and to help ensure that the study is accurately reported and interpreted.

Keywords: PBS, RCT, reliability, validity

Introduction

People with intellectual disabilities are disadvantaged by the societies in which they live in a myriad of different ways. One particular manifestation of this disadvantage is the failure to build a sufficient evidence base that identifies effective interventions for the commonly occurring needs of this population. Reflecting the general low priority often given to people with intellectual disabilities, this in part reveals a lack of interest in their welfare amongst many grant awarding bodies; simply put, interventions for disabled individuals will never compete with acute medicine or with interventions that potentially benefit the population as a whole when it comes to attracting research monies. The lack of data is, however, also a consequence of the practicalities of conducting robust research within this population and of the tension between 'gold standard' research methods used to evaluate relatively straightforward interventions, such as drug trials, and the complexity of multicomponent interventions typically in use with this group.

Mulhall et al (2018) make the cogent case for there being a need to have more randomised controlled trials (RCTs) on interventions for people with intellectual disabilities. They also, in a review of 53 existent trials, highlight specific difficulties in implementing such designs with intellectually disabled populations. These include the fact that randomisation – the process by which representative samples are randomly assigned to intervention or control groups – may be complicated

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by difficulties in identifying potential samples, problems in obtaining informed consent and ethical opposition to the use of control groups. Experimental control may be compromised by communications between participants, contamination of control groups, difficulty in engaging primary and secondary carers (who will often deliver any psychologically based intervention) and systemic variables (such as staff turnover). Finally, the trial component may also be impacted upon by the inability to use self-report measures and difficulties in participant attrition. Amongst their conclusions are that authors of RCT studies in the field of intellectual disability need to report on the barriers encountered during their studies more fully:

> *Although frameworks such as CONSORT provide guidance on how to report on the 'procedure' of a trial, they do not require reporting on the 'process' of the trial. (p.115)*

Mulhall et al also highlight the well-known problem of trying to apply research technologies designed to assess discrete interventions to those which are more multiply determined. They specifically state that:

> *It could well be argued that the RCT methodology is well suited to trials that test the efficacy of pharmacological interventions, eg does molecule A have a better impact than molecule B* under optimal conditions*. However, many researchers are less convinced that the methodology should be used to test the effectiveness of behavioural or psychological interventions, which are often effected* (sic) *by the myriad potential interactions between people* under real-world conditions*. (p.115)* (original emboldened text)

Though there is indeed a clash of research cultures between the methodology of the RCT and behavioural intervention, which has its foundations in single-case study design (Cooper et al, 2007), there have been recent examples where RCT methodology has been applied to positive behavioural support interventions (Hassiotis et al, 2009; Durand et al, 2013; Bradshaw et al, 2015). These have produced generally positive results, with impacts on challenging behaviour being evident in each study; importantly, in each case, interventions were delivered by practitioners with significant skills in delivering PBS interventions.

Further efforts to apply RCT methodology to PBS must therefore be welcomed as part of the quest to improve the evidence base for effective interventions for people with intellectual disabilities who demonstrate behavioural challenges. Hassiotis et al (2018a) have recently reported on the results of a multi-centre, cluster randomised control trial of staff training in 23 community intellectual disability centres in England using what was described as 'manual-assisted training' in positive behavioural support. Twenty-six staff were trained to deliver the staple components of the positive behavioural approach including conducting brief behavioural assessments, constructing primary and secondary prevention strategies, non-physical reactive interventions, behavioural trouble-shooting and quality monitoring. The primary outcome measure was reduction in levels of challenging behaviour and, contrary to previous studies, the results showed that no treatment effects were evident over a one-year period. It was concluded that 'the findings suggest that training the community intellectual disability staff in PBS, as delivered in this study, was no more effective than TAU (treatment as usual) in reducing challenging behaviour' (Hassiotis et al, 2018a, p164). Improving quality of life is of course also a central outcome in PBS. Though not mentioned in the initial paper, Hassiotis et al (2018b, pxxvi) reported that although there was evidence that the training was cost-effective as a result of improvements in quality of life, these improvements were not maintained at 36-month follow-up.

The authors commendably report a number of difficulties with the study process that may have impacted on outcomes; these touch on the problems of randomisation, experimental control and trial delivery outlined by Mulhall et al, but focus in particular on implementational difficulties.

The present paper is written by the external consultants who were charged with delivering the training and its aim is to comment further on the difficulties raised by both Mulhall et al (2018) and Hassiotis et al (2018a, b) with a view to making recommendations as to how future RCTs in this area could be improved. It supplements the data-based outcomes of the main study with a more reflective, qualitative account from the perspective of the behavioural intervention agent in an RCT study. The paper will focus on six separate but related aspects of the work: the training intervention, complexities with the training, the training mediators, training implementation, the control arm and the interpretation of the results.

The training intervention

Any interpretation of the study requires a full understanding of the trial intervention, which in this instance was the delivery of a short-form training in PBS to naïve participants. The training was delivered to two separate cohorts of staff in the form of three two-day workshops spaced approximately six to eight weeks apart. The objective was to focus on developing core skills to enable participants to work effectively with persons presenting moderate levels of challenging behaviour, the assumption being that more complex behaviours would require levels of intervention beyond the resource remits of the participating subjects. The first workshop focused on behavioural assessment and was built around the use of the Brief Behavioural Assessment Tool, a short form of semi-structured functional behavioural assessment interview designed specifically for use by staff in front-line community services and who do not have an advanced knowledge of behavioural analysis (Smith and Nethell, 2014). The second workshop concentrated on designing positive behavioural interventions and the third on potential difficulties in implementation, corrective actions and quality assurance.

All training materials were consistent with the definition of PBS given by Gore et al (2013) and had been previously tried and tested both within specialist services for people with intellectual disabilities and complex behavioural needs and within front-line community services. They were delivered by staff with significant experience of working in specialist behavioural intervention services (comprising specialist community behavioural teams, acute admission units and long-stay residential services) that had been subject to both internal and independent evaluation over an extended period of time (Allen et al, 2011; Perry et al, 2011, 2013; Lowe et al, 1996, 2007). The interval between workshops was designed to allow staff participants to submit a pilot behavioural assessment (between workshops I and II) and pilot behavioural support plan based on this assessment (between workshops II and III), and to receive detailed written feedback on both prior to commencing the main study. Workshops were interactive and featured 'bite sized' didactic presentations, each of which was followed up with individual and group exercises designed to teach key competencies.

Participants received handouts of all workshop presentations plus a professionally printed 186-page manual that provided additional material on the course content. It must be stressed that this was not a manualised training, however, and that the manual was merely an adjunct to the face-to-face training. Estimates of the time commitment required to complete an individual intervention were derived from previous experience of delivering the training. Post-training, each participant was offered mentoring support from one of the course tutors. In the first six months this involved the opportunity to submit one further complete case (ie a completed behavioural assessment interview, additional direct observational data, a PBS support plan and a completed goodness of fit checklist (adapted from Albin et al, 1996)) and two hours' support per month in terms of reading and feeding back on submitted work. In the second six months, one hour's support per month was available so that any technical or theoretical concerns concerning assessment, intervention planning or implementation could be raised with the training team. Mentoring took place by email and/or by telephone. In addition, monthly teleconferences were scheduled with local investigators (who played a co-ordinating role for each trial cluster) and the PBS trained staff in order to support and encourage compliance.

While it is entirely possible that this training was, as Hassiotis et al (2018a) conclude, an ineffective intervention, there were a considerable number of difficulties with the study which meant that drawing such a conclusion is not tenable. The remainder of the paper aims to highlight these issues.

Difficulties with the training intervention

An obvious immediate concern is whether a six-day training programme is sufficient to teach inexperienced staff the basic elements of the positive behavioural approach. It can probably be said with some confidence that it is not, but it is a pragmatic training period for staff whose primary responsibility is not to deliver PBS interventions in the course of their normal role (see below). The training intervention clearly surpassed that delivered in 38% of the studies with a known training duration reviewed by MacDonald and McGill (2013) and closely approximated that of a further 30%; only 30% of the studies in the latter paper significantly exceeded the training intervention in the present study. While a longer training intervention may have produced better results, it would not have been generalisable to real-world conditions, therefore; we also doubt whether extending the training in isolation would have made any difference given the complications reported below.

Though the staff participants 'rated the training and mentoring arrangements highly' (Hassiotis et al, 2018a, p165), a fundamental problem with the study was the failure to include a pre-post training measure of participant knowledge of PBS. In most training evaluations such measures are the only metrics taken. In the present study, the failure to collect such data means that there is no way of knowing whether the primary intended effect of the training (increasing participant knowledge and skills) was achieved; against such a failure, interpreting the secondary effects of the training (its impact on the challenging behaviours of service user participants) is deeply problematic.

Complexities arose with the intervention from the outset in that a number of staff participants attending the training seemed unaware of what was expected of them. They were typically surprised that they were initially committed to complete assessments on up to ten clinical cases (Hassiotis et al, 2018b, state that the requirement was eight cases), design a PBS plan based on these assessments and implement this plan in practice. Many became anxious about their obligations to the study when these requirements were fully explained, seemingly fully for the first time, when they attended the first day of training. Several had no real understanding of what the training entailed and no knowledge that they were expected to implement the training let alone submit practical work-based assignments. Some commented that this would be impossible and viewed the process with considerable scepticism as a result.

Very few participants submitted the required behavioural assessments and intervention plans between workshops, meaning that a key formative opportunity for feedback was immediately lost, thereby requiring some redesign of the subsequent workshop structure (given that the second and third workshops were predicated on the expectation that these assessments and interventions would be available to be worked on in class). Critically, participants' failure to complete these initial work activities were not a good omen for the remainder of the study.

Training therapists

The staff participants in the study were self-selecting and, for the most part, comprised NHS practitioners who would not normally be expected to lead the delivery of a functional assessment and comprehensive PBS intervention within the scope of their normal job (such as psychiatrists, nurses, occupational therapists and speech and language therapists); there was only one clinical psychologist in the group. The motivation of some participants to fully engage with the training may therefore not have been optimum given that it did not fit with their existing or post-trial roles.

Crucially, though 'Clinical managers in each cluster were asked and consented to reducing the routine caseload of the staff who volunteered to train by about 30% to allow them sufficient time to deliver enhanced treatment to the trial participants' (Hassiotis et al, 2018a, p162) 'several' participants reported organisational difficulties that included '(problems) with obtaining overtime pay for study related work', 'dissatisfaction with study-related amount of work in addition to overall caseload' and a 'lack of time to take on work relating to the study' (Hassiotis et al, 2018a, p165).

Despite the assurances of local managers, it was our experience that most participants had to carry out their study commitments on top of what were already significant existing caseloads, with study work often having to be completed in participants' own time as a result. It goes without saying that these were hardly conducive conditions to effective implementation. The fact that the study interventions were competing with the potentially more pressing demands of normal caseloads meant that they were always going to be low priority.

Implementation difficulties

The process of randomisation in an RCT is complex and can lead to delays in allocation to the trial and treatment as usual (TAU) arms, as happened in this case. As Hassiotis et al (2018a) note, there were several impacts of this delay, including service user participants in the trial arm not presenting with behavioural challenges at the point of study contact or PBS plans having been already introduced by third parties, meaning that further intervention was redundant (pp165–6).

Despite one of the two exclusion criteria being 'clusters which had embedded PBS therapists of local specialist teams' (p162), one cluster in the trial arm, which actually included the most enthusiastic participants, did have such a specialist team. There were also some qualitative indicators that staff in the trial arm were already using PBS methodologies with comments such as 'The PBS (training) and what we do are the same and the only real difference was the tool we used and then how we wrote it up in the first person' (Hassiotis et al, 2018b, p42), suggesting that further contamination had occurred.

Other difficulties reported by participants included being unable to access informants to conduct initial functional assessment interviews; several reported that agencies paying staff on zero hours contracts were unwilling to fund time to allow interviews to be completed. High turnover of direct care staff (42% in the trial arm) and the frequent use of temporary peripatetic staff was also cited as an impediment to plan implementation and some service user participants refused to engage with the trained staff. Several staff participants also reported that the assigned work was taking considerably longer than planned

The take up of the post-training mentoring opportunities was extremely variable, with some participants making good and others no use of the opportunity. Because of their awareness of the difficulties that participants were experiencing, mentoring arrangements were more flexible than originally planned with, for example, participants being able to submit multiple cases for consideration if requested. A total of 28 cases were flagged during the mentoring process, 96% of which had at least one completed BBAT assessment. In only 32% were any observational data collected, draft PBS plans were submitted in 57%, and no goodness of fit checklists were received. Revised PBS plans were rarely submitted for consideration post-feedback; in a further 25% of cases, elements of the intended interventions were received by the researchers but not seen by the mentors. One participant who was also a principal investigator and co-author in Hassiotis et al (2018a), submitted nothing during the training, only one partially completed BBAT post-training, and made no contact with their mentor during the 12-month study period. Overall, verifying how well the taught programme was taken on board was therefore extremely challenging.

With some notable exceptions, the monthly teleconferences were very poorly utilised, the range of attendees being 0–4. Many local investigators never took part therefore, although the research team maintained other contacts in an effort to improve compliance. Some participating staff also reported a disconnect between themselves and the local investigator, primarily in relation to there being a failure to appreciate the extent of the study commitments. There were also serious adverse events (primarily hospital admission for physical health needs) that occurred in both the trial and TAU arm, though a higher proportion of these occurred in the former. There was no difference in attrition rates between the arms. Of 26 trained staff, eight left the study through reasons of illness, maternity leave, and job changes; some staff also missed whole workshops for similar reasons.

The net outcome was that, out of a possible total of 108 interventions in the trial arm, only 33 included all four key elements: a completed behavioural assessment interview, additional direct observational data, a PBS support plan and a completed goodness of fit checklist.

While a fairer test of the intervention would perhaps have been to assess outcomes for these cases alone, the fact that the intervention plans were adjudged to be of poor quality by an independent assessor using the Behaviour Intervention Plan Quality Evaluation Scoring Guide II (Browning Wright et al, 2013) may have meant that this would have little impact upon the results. No data were collected on whether or not the derived plans were actually implemented. This leaves the possibility that, even in the 30% of cases where all the required components were present, the interventions were plans on paper rather than plans in practice; by definition, any intervention which is not delivered will have no impact.

A further 47 cases included between one and three of these elements, and nothing was submitted for the remaining 28 cases. In 43.5% of cases, the only input was primarily initial observations. What constituted such observations is not defined and any such observations could not in any case be expected to impact on levels of challenging behaviours; including them as interventions is therefore clearly problematic.

Control arm contamination

As stated above, there was at least one example of contamination of the treatment arm. Whilst the validity of the trial arm is of concern, so is that of the control arm which received 'treatment as usual'. Hassiotis et al (2018a) reported that:

> *TAU included any treatment approach that is available to community intellectual disability teams within the National Health Service. Most services in England employ a variety of health and social care professionals, and patients have access to behavioural, psychosocial and pharmacological interventions, e.g. physical health checks, simple behavioural modification, and prescribing and monitoring of psychotropic medication. None of those treatments is strongly evidence based but there is sufficient guidance concerning 'what good care looks like' (p162)*

The authors also note that 'It could be argued that gradual adoption of PBS-based care in some of the clusters in the TAU arm over the study duration may have reduced any differential between the trial arms' (p166) but dismiss this possibility as unlikely.

No actual data were collected on what services in the control arm were delivering, however, and, given the policy profile of PBS over the last decade and the increasing delivery of PBS training through a number of UK agencies and academic centres, it is entirely conceivable that the differences between the trial and control arms were not as pure as the methodology would suggest, thus further invalidating the comparison between the groups if so. Hassiotis et al (2018b) noted, for example, that within the TAU arm 'In some cases, the participants lived in accommodation where paid carers were PBS aware, that is, the accommodation provider had offered PBS-awareness seminars or employed an external consultant to advise care staff on PBS' (p8). Given that local services would have had more time to invest in staff development than was available in the trial, it is even possible that some services in the TAU group received more PBS training than was possible for the treatment arm.

Interpretation

This study represented a significant and expensive effort on the part of the research team, the trainers and many of the participants, but this combined effort resulted in disappointing outcomes. This result needs to be properly interpreted within the context of RCT methodology, however.

As stated above, RCT studies have traditionally addressed the impact of medications. If the analogy of a drug trial is pursued, the staff participants in the present research were trained to administer what many experts feel is currently the most effective 'drug' for the condition under study. But they varied significantly in their compliance with this training and, as a result, the formula was changed in some instances, the medication not given at all in others or not given at the time or rate prescribed, and sometimes a completely different drug delivered. In addition, some of the intended recipients were already in receipt of a version of the drug before the study intervention commenced, the drug was probably administered to some of the treatment as usual group and others did not have the condition for which the drug is recommended. One clearly cannot draw any conclusions about the drug's efficacy under these circumstances, and to claim otherwise would be clearly misleading. While Hassiotis et al (2018) dismiss previous reports of significant effects of PBS training as being 'likely due to study bias', it is just as possible that other studies got both the dose and administration correct and were conducted in more favourable environments than that described here.

Conclusions

This was an interesting, if difficult, project to work on from a number of different perspectives. First, the study was delivered in a post-Winterbourne policy context that placed great emphasis on the role of PBS in providing effective services for people who challenge. Second, the project sought to apply a methodology (the RCT) to an area of work that has historically been founded upon the single-case study and meta-analysis. Third, the participating staff group were mostly made up of practitioners who would not traditionally be charged with leading the delivery of PBS interventions. Fourth, we were attempting to skill up these practitioners in (mostly) unfamiliar skills and over a relatively short period of time. Fifth, the receiving environments often seemed less than optimum.

The project was about the efficacy of training unfamiliar community support team staff in a short course of PBS; it was not about the effectiveness of PBS per se and certainly not, as Hassiotis et al (2018b, pxxiii) suggest a 'definitive trial' for the 'efficacy of PBS' in 'pragmatic conditions'. It was therefore disappointing to see some authorities commenting freely that 'PBS did not work' at a conference reporting the initial results, and others pursuing this agenda subsequently. The study demonstrated all the potential difficulties that might be experienced in an RCT as described by Mulhall et al and a critical point to grasp is that, just as a training intervention cannot compensate for major deficiencies in a service environment, it cannot overcome significant procedural issues in a research study.

The study reported some paradoxical findings in the sense that no behavioural changes were evident but short-term gains in quality of life were. Though there is a possibility that the intervention may have been sufficiently powerful to obtain gains in this area, though not on the primary clinical measures, the poor implementation makes this unlikely.

While critics will argue that short-form training in behavioural intervention has no place beyond awareness raising, such training has a long history in terms of trying to 'give away' the behavioural approach; a number of

eminent PBS practitioners run less-intensive courses than the ones delivered here and have successfully done so now for many decades. As detailed above, the training involved rather more than simple didactic training interventions and, as we have argued, was probably realistic in terms of duration and content for the audience concerned. Furthermore, as previously stated, it closely approximated the duration of many of the studies reviewed by MacDonald and McGill (2013) and it also followed a longitudinal form that, in theory at least, allowed for the practice of skill between training and post-training events. A re-consideration of the optimum structure for the training intervention should nevertheless be top of the list of considerations for anyone seeking to replicate the present study but, for the reasons specified above, it cannot be concluded from this study that short-form training has no role to play in building cultures of positive behavioural support.

Other considerations emerging from this paper include the need to:

- select staff participants for whom PBS has more relevance to their normal and future clinical practice
- make clear to all staff participants exactly what their commitment is before they sign up to participate in the study; individualised pre-research contracts may be helpful in this respect
- include pre-post training tests of knowledge
- adhere to trial rules about exclusion from active treatment arms
- ensure that randomisation is completed accurately and in a timely fashion
- ensure that trial caseloads are genuinely substitutes for rather than additions to normal caseloads
- collect data on implementation fidelity of intervention plans (both in the short and longer-term)
- collect data on interventions provided in the control condition
- develop better links between local investigators and the central research team and between local investigators and staff participants
- train whole staff teams rather than individuals (as the latter may struggle to introduce PBS in non-PBS service environments)
- develop more formalised means of mentor follow-up for staff participants.

A trial of PBS itself would clearly look very different to the RCT described by Hassiotis et al (2018), the most critical point being that the assessment and intervention process would be undertaken by practitioners with proven expertise in the field rather than novices (as was the case in the studies by Hassiotis et al, 2009, Durand et al, 2013, and Bradshaw et al, 2015 cited above). They would also be given adequate time and space to work through the fundamental components of the approach, with service users that demonstrated significant levels of pre-intervention behavioural challenges, with direct observations being utilised in addition to rating-based assessments of outcome, and with services that were amenable to intervention rather than ones that appeared to be struggling to maintain their operations. The literature on specialist intervention teams who use this model, though sparse, is therefore a fairer test of PBS than the study described here. The study does support the need for a more informed and comprehensive view of developing the skills of the workforce in PBS, that involves detailed work on defining PBS competencies, planning and delivering a national training infrastructure, creating cultural change, and evaluating training and service outcomes (Denne et al, 2015).

The study also comments indirectly on the general state of services in England for people with intellectual disabilities and challenging behaviour and what constitutes 'treatment as normal'. The difficulties in implementing complex interventions such as behaviourally based ones are well-known; the challenges of doing so in a culture of austerity and zero hours contracts make this increasingly difficult and perhaps helps ensure that easier to administer, but less effective interventions and/or interventions with more side effects, become increasingly the norm. Similarly, while staff participants in the present study found the implementation demanding, both the assessment and intervention components were short forms of PBS designed for use by teams working in the front line of community care. If even these more tailored forms of intervention are not feasible in front-line community services for whatever reason, then it will result in increasing numbers of service users having to be directed to more specialist services for even basic forms of behavioural support – a hugely concerning prospect. It would also be useful to check out whether there is a national consensus about 'what good care looks like' for people who challenge on the front line of services.

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