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Psychological interventions in forensic learning disability services:

A focus on anger and aggression

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Word Count Statement

Thesis Section	Text	Abstracts, Footnotes, References, Tables, Figures and Appendices	Total
Abstract	296	-	295
Literature Review	7,995	10,671	18,666
Research Paper	7,999	4,665	12,664
Critical Appraisal	3,987	863	4,850
Ethics Section	5,398	3,133	8,531
Totals	25,674	19,305	44,979

Thesis Abstract

Difficulties with emotion regulation are reported as commonly experienced by people with intellectual disabilities (PWID). These difficulties can lead to the involvement of PWID with forensic services, and the requirement for them to undertake psychological therapies aimed at improving their regulation of emotion. This thesis firstly provides a critical review of the quantitative evidence for the effectiveness of interventions addressing the most prevalent form of emotion dysregulation for PWID in community-based and inpatient forensic services: anger and outwardly-directed aggression. Sixteen studies met the inclusion criteria and offered promising evidence for the effectiveness of a range of psychological approaches in improving anger and reducing aggression. However, firm conclusions and generalisability of findings were precluded due to the pervasive methodological shortcomings across studies, and accordingly, recommendations for future research and service providers were made.

Second, this thesis empirically explores the process of engagement and perceived change for PWID in forensic services attending dialectical behaviour therapy (DBT). The perspectives on "what works" in DBT are gathered via interviews with nine participants and analysed using a constructivist grounded theory-informed methodology. The resultant model highlighted a temporal process within which participants encounter a difficult and coercive journey from compliance and avoidance, to acceptance and integration of change. The model was discussed in relation to current theory on the process of change, and clinical implications were made in respect of improving the support provided to PWID attending DBT in forensic settings. Future research is encouraged to explore and address perceived coercion and aversive elements within psychological interventions for PWID, to enhance treatment experience, effectiveness and evaluation.

Finally, reflections were offered in the critical appraisal section of this thesis on the potential challenges of conducting research with PWID in forensic settings and the recurrent theme of coercion noted in respect of this population.

Declaration

This thesis reports research undertaken between June 2015 and August 2016 as a requirement of the Doctorate in Clinical Psychology at Lancaster University. The work presented here is the author's own, except where due reference is made. The work has not been submitted for the award of a higher degree elsewhere.

Claire Browne

August 2016

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I could not have completed this thesis without the help and support of many people.

Firstly, I am grateful to the nine individuals who gave up their time to take part in the research. I hope that my study does justice to the perspectives and experiences you generously shared with me. I would also like to thank the services who facilitated my project, in particular Cath, Scott and Michelle for their willingness, enthusiasm and help.

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To my greatly neglected and much missed family and friends, thank you for your tolerance and encouragement. I owe a special thanks to my mum, for your unwavering belief and care, and to Lucy, for all the help you gave me in so many ways.

Finally, my greatest thanks of all goes to Paul for your unconditional support, infinite patience, and real understanding – we've been on a long journey!

This thesis is dedicated to Adrian Browne; I know you are proud.

Contents

Chapter 1 : Literature Review

Psychological interventions for anger and aggression in people with intellectual disabilities in forensic services: A systematic review of the literature

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[1] Please refer to Appendix B for journal instructions to authors

Abstract

This systemic review aims to investigate the effectiveness of anger and/or aggression interventions for people with intellectual disabilities (ID) in forensic services. Due to the prevalence within this population of difficulties with anger and aggression, and the associated substantial individual and societal consequences, the provision of psychological interventions has become increasingly common. However, no critical synthesis of the empirical evidence relating to their effectiveness has been conducted, despite the need for evidence-based practice. Relevant bibliographic database and hand searches were conducted to identify quantitative literature relating to the aim of the review. Sixteen peer-reviewed studies, published between 2001 and 2016 and using controlled trials or case series designs, met the inclusion criteria. The results highlight an emerging evidence base for the use of CBT in improving anger regulation, and for a range of psychological therapies in reducing aggressive behaviour. However, consistent methodological shortcomings limit the generalisability of findings and currently preclude firm conclusions on effectiveness. Recommendations for future research to address these shortcomings and inform evidence-based interventions for people with ID in forensic services are made. Given the current status of evidence, implications for service providers and clinicians providing anger and aggression interventions to people with ID are further discussed.

Keywords:

Systematic review

Intellectual disabilities

Forensic

Anger management

Aggression

Psychological interventions

1. Introduction

Anger is a universally accepted emotion, triggered by negative appraisal of a perceived threat, which leads to increased physiological arousal (DiGiuseppe & Tafrate, 2007). Although an adaptive survival mechanism (Novaco, 2013), anger becomes problematic when experienced intensely, recurrently or for prolonged periods, or when expressed in violation of sociocultural norms, such as through aggression (Taylor & Novaco, 2013). The term aggression is often used interchangeably with anger despite the two constructs being distinct: with anger an emotion and aggression a behaviour (Spielberger, Reheiser, & Sydeman, 1995). Specifically, aggression is defined as any behaviour directed towards others that is intended to cause unwanted harm (e.g., Geen, 2001), including verbal and physical intimidation or violence and property destruction.

Research has shown anger as a substantial activator of aggression, for example, through reducing inhibitions and maintaining arousal to aggress (Anderson & Bushman, 2002). Furthermore, anger and aggression are reciprocally-influenced, with aggressive behaviour generating as well as assuaging anger (Konecni, 1975). However, anger is "neither necessary nor sufficient" for aggression to occur (Novaco (1994, p. 33), with aggressive behaviour an interaction outcome of situational, biological, psychological, and social factors (Anderson & Bushman, 2002).

1.1 Anger and aggression in people with intellectual disabilities

Difficulty regulating anger and its subsequent expression through aggression is reported as a substantial problem for some people with intellectual disabilities (PWID) and may occur at a higher rate than in the non-ID population (see Hagiliassis, Gulbenkoglu, Di Marco, Young, & Hudson, 2005). Indeed, community prevalence surveys indicate estimates for problem anger ranging from 10% to 16% in PWID (see Taylor & Novaco, 2013), in comparison to 7.8% in a non-ID sample representative of the US population (Okuda et al.,

2015). Within the ID literature, difficulties with anger and aggression are often subsumed under the term challenging behaviour (Emerson, 1995), which describes a broader range of socially unacceptable actions including sexually inappropriate, stereotyped or self-injurious behaviour. This review focuses on anger and outwardly-directed aggression, the most prevalent and problematic challenging behaviours displayed by PWID (Emerson & Einfield, 2011).

Taylor and Novaco (2013) suggest greater anger dysregulation among PWID is induced by their often adverse life experiences. Consistent with prior research, a recent study found PWID are at least seven times more likely than the non-ID population to have sustained childhood abuse, and that 50% of the sample had been assaulted as adults (Catani & Sossalla, 2015). These experiences create vulnerabilities to increased anger, misattributions of hostility, and normative beliefs about and modelling of aggression, in turn forming barriers to learning prosocial coping skills (Novaco & Taylor, 2008).

Furthermore, Taylor and Novaco (2013) highlight the exposure of PWID to pervasive restrictions on their autonomy, privacy, relationships and activities. These constraints can result in unmet physical, emotional and interpersonal needs, consequently potentiating anger and eliciting aggression as a means of escape, communication, or securing requirements (Matson & Kozlowski, 2012). However, the display of aggression is likely to lead to increased restrictions, thereby creating a cycle in which the quality of life for PWID is further reduced and their aggressive behaviour potentially perpetuated (Sturmey, 2002).

Indeed, PWID who display aggression are reportedly less satisfied with their lives than those who do not (Murphy, 2009), with a reduction in aggressive behaviour linked to improved quality of life (Hatton et al., 2004). Dysregulated anger and aggression are significant predictors of social rejection and loss of community access for PWID (Bigby, 2012), and correspondingly, the main reason this population are referred to inpatient mental

health services (Stern, Fava, Wilens, & Rosenbaum, 2015). Within such settings, anger and aggression increase the likelihood of PWID being detained for prolonged periods in out-of-area placements (Allen, Lowe, Moore, & Brophy, 2007), prescribed medications with serious potential side-effects (Lundqvist, 2013), and physically restrained and secluded (Merineau-Cote & Morin, 2013).

1.2 Anger and aggression within ID forensic services

Aggression is the most common reason for admission to forensic services for PWID (Lindsay et al., 2103). Comparing populations detained in forensic settings, a significantly greater proportion of aggressive incidents are perpetrated by PWID than by those without (Dickens, Picchioni, & Long, 2013; Turner & Mooney, 2016). Similarly, greater use of aggression has been found in people in forensic ID services (PFID)[2] than ID adults in non-forensic settings (Larkin, Jahoda, & MacMahon, 2013; Nicoll & Beail, 2013). These findings highlight the substantial and chronic problem of aggression for PFID. Nicoll and Beail found no anger differences between the ID groups, although acknowledge a number of potential confounds to their results. If the anger level of PFID is similar to their community-based peers, it may still be regarded as higher than in the general population.

Given that a lack of attachment security is suggested to predispose and perpetuate the anger dysregulation and aggression of PFID (Fletcher, Flood, & Hare, 2016), such individuals would likely benefit from developing secure relationships with staff. However, a systematic review of ID adult aggression found it elicits in staff feelings of hopelessness, anger, fear and disgust, manifesting as increased indifference and restrictive practices, thereby reinforcing the poor attachments, and anger and aggression, of PFID (Lambrechts, Petry, & Maes, 2008). Correspondingly, staff working with ID aggression can endure job

[2] Although the terminology *ID offender* is frequently employed within the literature, this review instead utilises *people in forensic ID services* (PFID) in reference to intellectually disabled adults who are subject to forensic service pathways. This distinction acknowledges that many such individuals have not committed or been convicted of criminal offences but are deemed to have forensic needs due to judgments around the risk of harm they pose to others.

dissatisfaction and burnout (Kozak, Kersten, Schillmöller, & Nienhaus, 2013), but may also sustain injury, resulting in increased sickness leave and strain on already under-resourced workforces (Winstanley, 2005). Indeed, the sole forensic ID Trust within the UK's National Health Service has the highest number of assaults per 1,000 staff (NHS Protect, 2015) and highest mental health service staff sickness rate (Health & Social Care Information Centre, 2015).

The aggression displayed by PFID has not only substantial ramifications for the individual and staff who support them, but also for services through the associated costs of providing greater staffing levels to manage incidents (Chaplin, 2004) and cover sick leave, injury compensation, and recruitment due to high staff turnover (Singh et al., 2008). With the majority of PFID detained in government or state facilities, such costs are also a burden on the taxpayer. These personal and financial expenses, coupled with the clear detriment to the efficacy of forensic services to be of therapeutic and rehabilitative value, makes addressing anger and aggression through effective interventions of vital importance (Tenneji & Koot, 2008).

1.3 Interventions addressing anger and aggression

Historically, interventions targeting anger and aggression in PWID involved psychopharmacological treatment. However, a review by Willner (2015) concluded "there is no reliable evidence that antidepressant, neuroleptic or anticonvulsant drugs are effective treatments for aggression" in PWID (p. 82). Weak evidence was suggested for an antipsychotic that has significant side-effects and, in one study, was less effective than a placebo (Tyrer et al., 2008). Given the, at best, equivocal evidence coupled with potential toxicity and expense (Unwin, Deb, & Deb, 2016), the National Institute for Health and Care Excellence (NICE, 2015) recommend antipsychotic medications should only be prescribed should psychosocial interventions prove ineffective.

Such psychosocial interventions typically draw on behavioural approaches, with meta-analyses having shown some evidence of their effectiveness in reducing aggression (see Heyvaert, Maes, Van den Noortgate, Kuppens, & Onghena, 2012). However, this evidence is largely drawn from interventions for individuals with severe ID, targeting self-injurious and stereotypic behaviours. This has led Taylor and Novaco (2005) to question the effective transferability of these behavioural approaches to PFID who tend to be relatively high functioning and display more outwardly-directed aggression. Furthermore, behavioural approaches are usually implemented by staff, limiting opportunity for PFID to develop self-regulation skills: a necessary requisite to achieve progression to lower conditions of security or community discharge (Kitchen, Thomas, & Chester, 2014).

1.3.1 Psychological interventions

Within the non-ID population, psychological interventions for addressing anger dysregulation and aggressive behaviour are the most frequently delivered treatment in forensic services (Howells et al., 2005). These typically utilise cognitive behavioural therapy (CBT) and have amassed a substantial evidence base producing medium-large effect sizes (Henwood, Chou, & Browne, 2014). While CBT is most commonly utilised, meta-analyses and systematic reviews also support other therapeutic modalities, including psychodynamic (Saini, 2009) and dialectical behaviour therapy (DBT) (Frazier & Vela, 2014), in treating anger and aggression across forensic non-ID settings.

In comparison, PWID have only in recent decades been provided access to psychological interventions, with this population traditionally excluded due to discourse around cognitive difficulties as an insurmountable barrier to engagement and success (Bender, 1993). With these prejudicial beliefs since disputed and, at least in the UK, now contravening equalities legislation and government policy (Joint Commissioning Panel for Mental Health, 2013), access for PWID to psychological therapies is improving (Beail,

2016). The interventions available tend to mirror those used in the general population, yet if delivered without adaptation can prove inaccessible, obstruct treatment gains and increase attrition (Pitman & Ireland, 2003).

The adaptations suggested to maximise the accessibility of psychological interventions for PWID focus on aiding comprehension, retention and generalisation through concepts being broken down and explained using simplified language, the use of non-verbal techniques and visual materials, and frequent repetition and rehearsal (see Lindsay, Jahoda, Willner, & Taylor, 2013). An evidence base for adapted psychological approaches for PWID is emerging, within which the treatment of anger has become one of the most widely researched areas (Willner, 2007) and includes a number of systematic and meta-analytic reviews (see Ali, Hall, Blickwedel, & Hassiotis, 2015; Borsay, 2013; Hamelin, Travis, & Sturmey, 2013; Nicoll, Beail, & Saxon, 2013; Vereenooghe & Langdon, 2013). However, none of these reviews have focussed specifically on PFID and some actively excluded studies employing forensic samples due to the differences this population and their environment present. The narrative reviews that have been undertaken in this area (Taylor, 2002; Lindsey & Taylor, 2005) are open to biases in that they were conducted by the author/s of a number of the included treatment studies, and provide no rigorous quality assessment of the evidence on which they base their conclusions.

As noted, while anger is an established antecedent of, it is not necessary for, the display of aggressive behaviour. Nicoll and Beail (2013) highlight how treatment for PFID assumes that the aggression that led to their detention results from elevated anger and thus anger interventions are necessary to reduce recidivism. However, finding no difference in anger between PWID in forensic and non-forensic settings, Nicoll and Beail question the "rationale that reduction in anger levels…would reduce aggression/offending behaviour" (p.

468). Indeed, evidence for the association between anger treatment and reduced aggression is limited (Novaco & Taylor, 2015).

1.4 Aims of the review

The literature base indicates that PFID display chronic, problematic aggression, which is increasingly being addressed using anger interventions. However, no published systematic synthesis of the available empirical evidence relating to the effectiveness of such treatment has be conducted, despite the clear need for evidence-based interventions at the individual, service and societal levels.

Thus, the aim of this review is to systematically locate and summarise current relevant research through a methodologically rigorous investigation. In doing so, the review addresses the question: What is the evidence for the effectiveness of psychological interventions targeting anger and/or aggression in PFID?

2. Method

To ensure rigour and transparency, the review was guided by recommendations of the Centre for Reviews and Dissemination (CRD, 2009) and the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA; Moher, Liberati, Tetzlaff, & Altman, 2009).

2.1 Inclusion/exclusion criteria

To be included in the review, articles had to: (a) be published in English language; (b) have recruited a sample of adults (≥ 18 years) with ID; (c) have recruited participants in community or inpatient forensic services; (d) report on the effectiveness of a psychologically-based intervention addressing anger and/or aggression.

Articles were excluded if they: (a) did not report on intervention (e.g., descriptive papers), (b) did not provide outcome data relating to anger or aggression, or (c) included undifferentiated data from both forensic and non-forensic services.

In line with the author's epistemological stance (see section 2.3), studies were not excluded on the basis of methodology or publication status. From a critical realist position, the test for inclusion is whether the evidence a paper provides is good and relevant enough (see Pawson, 2006), and that a variety of sources should be considered to effectively uncover "as much of reality as possible" in relation to the review question (Denzin & Lincoln 1998, p.9). Despite this approach, no qualitative studies were located. It is, however, on this basis that studies providing only descriptive statistics were not excluded.

2.2 Search procedure

Relevant studies were identified by means of comprehensive searches of the electronic databases PsycINFO, Academic Search Complete, Scopus, PubMed and Web of Science, from their inception through to and including May 2016. Databases were selected for providing comprehensive coverage of the literature published in this area.

The key concepts under review—ID, anger and aggression interventions, and forensic settings—were explored, where available, within database thesauri to identify the subject headings used to index these concepts and generate search terms for explosion. Subject headings and their exploded terms differed according to specific database indices, for example, in respect of ID PsycINFO uses "intellectual development disorder" whereas Academic Search Complete employs "Mental Disabilities". Free text searches were also performed using three sets of terms drawn from examination of related reviews and their included studies. The terms included within each free text search set are set out within Table A.1.

[INSERT TABLE A.1]

For both the thesaurus and free text searches, search sets were linked with the Boolean operator "AND" and the terms within linked with the instruction "OR" and a truncation asterisk applied in some instances to account for different permutations. Whole text searches were performed except within the Web of Science database, which does not offer this option, meaning that terms were searched for in the 'topic' field. With awareness of the variability of terminology and general paucity of research within the relatively new field of forensic ID, coupled with this being the first systematic review in this area and the underpinning critical realist stance, no restrictions other than that of adult participants (≥ 18 years) were applied.

The thesaurus/subject mapping searches yielded 665 papers, while the free text searches produced 713 articles, published between June 1914 and May 2016. After papers not published in English language were removed and duplicate articles screened out, 194 articles remained. Subject headings and free text terms were then combined, with search sets again linked by "AND" and terms within linked with "OR" and truncation asterisks applied. The combined search yielded 823 articles; however, after duplicates and non-English language papers were removed, the combined compared against the original search provided no new articles. A prolific author of literature within the field was contacted to identify any relevant publications in process, and the Cochrane Library also consulted: No additional articles were highlighted. The grey literature was explored and located one doctoral dissertation which had subsequently been published and the paper previously identified within the database searches. A number of relevant book chapters were identified; however, the interventions these made reference to had again been published within journals and located during the systematic searches.

The 194 articles generated were screened using the inclusion criteria, leading to 138 exclusions. Hand searching of the reference sections of relevant literature reviews and the

papers selected for inclusion, followed by examination of their citations, authors and of two journals commonly publishing relevant articles, identified a further 25 potential articles; 16 of which were excluded upon review. The full text papers of the remaining 65 studies were assessed, and further exclusions guided by inclusion criteria resulted in 16 studies being included in this review. An overview of this process using the PRISMA flow diagram template is depicted in Figure A.1.

[INSERT FIGURE A.1]

2.3 Epistemological position

As a researcher's epistemological stance will shape the way they conduct, interpret, and report their research, it is vital to identify one's position with regard to knowledge and its acquisition (Darlaston-Jones, 2007). The author's perspective is consistent with the critical realism philosophy that combines a realist ontology with a relativist epistemology. That is, while an external reality exists independently of human perceptions, it is experienced and interpreted though our subjective constructions (Bhaskar, 1998; Maxwell, 2012). Critical realists assert that our ascribed understanding of a phenomenon has coherence with reality if individuals' experiences are congruent with that understanding (Ryan, Scapens, & Theobald, 1992), which can be modified or refuted as research in the area progresses (Sayer, 2000). Thus, in synthesising the available empirical evidence relating to the effectiveness of anger and aggression interventions for PFID, this review "allows us to construct a consistent and coherent account" of this phenomenon (Churchland, 1979, p.87).

2.4 Assessment of quality

Central to critical realism is the premise that accuracy and transparency of evidence is necessary for a review to consider coherence and consensus (Ryan et al., 1992) and "the basis

on which inferences are made" (Pawson, 2006, p.93). Therefore, as the merit of any conclusions drawn on the effectiveness of interventions for PFID is dependent on the evidence produced by studies under review, their methodological strengths and weaknesses were assessed. For this purpose, the Effective Public Health Practice Project Quality Assessment Tool (EPHPP; Thomas, Ciliska, Dobbins, & Micucci, 2004) was selected. This standardised evaluation framework was designed for application against all quantitative designs, making it appropriate for appraisal of the selected papers which included controlled trials (CTs) and case series studies. Furthermore, the EPHPP has demonstrated content and construct validity (Thomas et al., 2004), largely encompasses the principal quality items identified by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement (von Elm et al., 2007), and has been endorsed by The Cochrane Collaboration (Higgins & Green, 2011).

Using the EPHPP, studies were rated "strong", "moderate" or "weak" on six methodological components: selection bias, study design, confounders, blinding, data collection methods, and withdrawals/dropouts. Seven of the studies were rated by an independent reviewer. High levels of agreement were found (92%) and minor disagreements discussed and resolved. The EPHPP dictionary, which clarifies each component and its quality criteria, was used to guide ratings except those for the study design component due to its automatic rating of CTs as "strong". Critical realists reject this positivist assumption of clinical trials as the "gold standard" of knowledge, highlighting that CTs can lack external validity in the complex social world and a more critical engagement with the evidence they provide is required (Marchal et al., 2013). In keeping with the critical realist assertion that it is the way a method is used, rather than the method itself, that is of importance (McEvoy & Richards, 2003), the study design scoring was modified: If a CT did not describe its

randomisation method or allocation concealment, it was downgraded from “strong” to “moderate”.

The six EPHPP component ratings were aggregated to assign each study a global quality rating. Studies classified as “strong” on overall quality achieved no weak component ratings, those classified “moderate” had one weak rating, and those classified “weak” had two or more weak ratings. The EPHPP and its accompanying dictionary can be found in Appendix A.

As this review aimed to comprehensively evaluate the literature and report on the relationship between study quality and yielded outcomes, no studies were excluded following quality appraisal. Furthermore, from a critical realist perspective, studies should not be excluded due to poor quality ratings as the true appraisal of a study’s worth is also informed by the synthesis of findings (Pawson, 2006). However, the results of the EPHPP evaluation were considered when interpreting the studies’ findings and thus informed conclusions made within this review.

2.5 Data extraction and synthesis

A specific protocol was designed to ensure information relevant to the review was extracted from each study systematically. The range of interventions and outcome measures within the studies reviewed were not considered sufficiently homogenous for statistical synthesis, thus a narrative analysis of findings is presented.

3. Results

Table A.2 provides an overview of the methodological characteristics and key findings of included studies, referred to hereafter by the number assigned within the table for brevity.

[INSERT TABLE A.2]

Two studies (9a-9b) report on the same group of participants and are regarded as a single study, reducing the total papers reviewed to fifteen. Both were retained due to their differing contributions to assessing effectiveness: Study 9a examined associations between reductions in anger and aggression, whereas 9b focussed on reductions in specific categories of aggressive behaviour. Additionally, the experimental group (EG) in study 11 comprised the combined control and experimental cohorts from study 12, resulting in data overlap for nine participants receiving intervention.

3.1 General characteristics

Adjusting for the data overlap of the aforementioned studies, a total of 274 participants took part in the 15 studies, with an additional 52 acting as controls. Studies were published between 2001 and 2016, and conducted in the UK, USA, and New Zealand. None were conducted in prison settings, which likely reflects the lack of anger interventions adapted for PWID in prisons (Bond, 2012; Oakes, 2013).

Two studies (11, 12) were RCTs and a further two (7, 13) non-randomised controlled trials (NRCTs): All had a waiting list control group (CG) who went on to receive the intervention. The remaining papers utilised pre-post case series designs. Eight studies provided self-report follow-up data from their entire sample for periods ranging from 1-15 months.

The level of ID or IQ range was reported by all studies, with the majority of participants having mild ID; none had severe or profound ID. The samples of two studies included participants who would not be classed as having an ID. In study 2, 17.5% of participants had full-scale IQs (FSIQs) in the Borderline range of ability; the remainder had mild or moderate ID. Three participants in study 5 had mild ID, while the remaining four had Asperger's syndrome and FSIQ's ranging from 77-111; individual participant data was provided and only that relating to participants with mild ID considered within this review

3.1.1 Measures

Specific outcome measures utilised in the studies are detailed in Table A.2. Ten studies employed self-report anger measures, completed at least pre- and post-treatment. Study 9a/b modified these to form structured participant interviews. Participants in two studies also completed anger-provoking roleplays and daily anger diaries. Additionally, three studies utilised a scale completed by ward staff, rating participants' anger over the past week.

Ten studies employed some measure of pre- and post-treatment aggression, including violent recidivism; staff-observed aggressive incidents; and/or self-report, ward staff or facilitator-completed questionnaire measures.

3.1.2 Interventions

Eleven studies employed CBT-based interventions. The remainder delivered DBT (2), mindfulness-based approaches (4, 10), or behavioural skills training (BST; 15). Six studies did not discuss whether facilitators were trained to deliver the intervention (1, 3, 6-8, 10). Studies 9-15 were delivered on an individual basis; study 2 incorporated individual and group sessions; and the remainder were group-based. Sessions ranged from 30 to 150 minutes, delivered over three weeks to 82 months.

All studies made reference to providing manualised or protocol-based treatment; 12 of which were developed specifically for PWID, while a further two (2, 5) described adaptations made to mainstream programmes to meet the needs of their participants. These modifications included simplification of written materials and terminology, the introduction of visual aids, and the augmentation of explanations. Study 3 delivered a non-modified mainstream intervention and reflected on the need to introduce adaptations to improve accessibility.

3.2 Quality

Using the EPHPP quality appraisal tool, six studies obtained an overall "weak" quality rating, 10 scored "moderate", and none achieved "strong" (see Table A.3[3]). Across the studies, strengths included the use of valid and reliable measures of anger and aggression, and the low attrition rates and explanations for drop-outs. There were consistent methodological limitations, the most prevalent being the lack of reported consideration of confounding variables.

No study considered the effects of comorbidity and psychotropic medication; however, studies 5, 11-12 excluded participants with acute mental health difficulties. Additional potential confounders, such as physical difficulties, pain, or life events such as recent admission, were not addressed by any study, although study 4 considered the impact of seasonal factors through descriptive data comparisons. Despite the substantial reliance on self-report measures, no study measured or controlled for social desirability responding. This confound is particularly relevant, first with PWID and second in forensic settings, where external, discharge-related factors may influence answers on outcome measures (Jobson, Stanbury, & Langdon, 2013) and conceal or decrease intervention effectiveness (Schamborg & Tully, 2015).

Three controlled trials (11-13) highlighted no significant differences between their EG and CG participants at baseline on age, IQ, length of detention, legal status, offence history, anger screening scores, and psychiatric diagnoses. Trials 11 and 12 further reported having balanced the groups on these variables following random allocation of participants. However, allocation concealment was not described, non-completer data not analysed, and intention-to-treat analyses not conducted, thereby reducing the original comparability of the treatment groups. The final trial (7) used a CG unmatched in respect of age and gender and

[3] Studies 9a and 9b were scored separately due to their use of different outcome measures and, therefore, different data collection methods.

did not control for pertinent variables, thus potentially introducing substantial error (Reeves, Deeks, Higgins, & Wells, 2011). In all trials EG and CG participants resided in the same inpatient settings. EGs may have shared intervention learning, or their improved self-regulation reduced anger-provoking incidents, therefore, it is difficult to conclude that treatment effects were confined to EGs.

It was not feasible to ensure participants were blind to the nature of the interventions. Independent observers blind to group allocation rated the roleplays in study 7, and research assistants again not involved in treatment delivery conducted the evaluations in the remaining controlled trials (11-13); however, they were not blind to participants' condition. Finally, eight of the 15 studies were conducted by researchers who can be considered as having vested interests through having written the treatment protocols utilised.

None examined treatment fidelity or researcher allegiance, nor was assessment of suitability for treatment reported. Eight studies included participants ranging from mild to borderline intellectual functioning and a further two included a small number with borderline to high average IQs, increasing heterogeneity and difficulty with sample comparisons. Three studies (2, 11, 14) did include intellectual functioning as an analysis covariate and found no significant differences. Finally, only study one discussed power calculations (4) and six reported effect sizes (4, 8, 9b, 11, 13-14). Attention to statistical power is particularly important in clinically relevant research, especially with the majority of studies having small sample sizes. Therefore, where available data permitted, effect sizes and 95% confidence intervals (CI) were calculated as part of this review.

[INSERT TABLE A.3]

3.3 Effectiveness of anger and aggression interventions for PFID

Most studies assessed change on either anger or aggression outcomes. Four studies utilised measures of both; however, three did not analyse associations between these outcomes. Consequently, the evidence pertaining to anger and aggression within these studies has been separated and is discussed under both the outcome subsections. The fourth study did explore whether improved anger, as an outcome of treatment, led to reduced aggression and, therefore, is discussed separately.

3.3.1 Anger regulation

The nine studies measuring change in anger experience all utilised CBT-based interventions. Almost half originated from a single research group (11-14) and used the same individual 24-session format, based on the ID-specific anger management manual by Taylor and Novaco (1999, 2005). The remaining five studies were group-based interventions, three of which were produced by one research group (1, 6, 7) utilising the same 40-session treatment format, while the final two independent studies (3, 5) had a treatment duration of 12-weeks.

The two RCTs (11, 12), both rated as "moderate" in quality, found greater decline in self-reported anger pre- to post-treatment for participants in the EG than CG. These between-group differences were statistically significant on the one measure utilised in study 12, and CG anger scores also worsened significantly. Effect size calculated for review exceeded Cohen's (1992) convention for a large effect, thus the significant finding was strong in magnitude, although partly masked by low measurement precision due to the small sample, as reflected by the wide CI [16.693, 40.107]. In comparison, study 11 employed three self-report anger measures and found significant interaction effects with medium effect sizes only for the NAS Total and Arousal subscale and the PI Unfairness subscale, maintained at four-month follow-up. Given the small sample size, the non-significant findings potentially reflect

the study's acknowledged limited statistical power. However, the study's authors also observed confounders, namely positive differences in direct-care staff responses to anger displayed by both EG and CG, and the sharing of skills by the EG with the CG. These likely contributed to the unexpected improvement in CG anger scores, and masked intervention effectiveness.

The staff-rated anger measure employed by these two RCTs similarly noted improvements for the EGs compared to CGs; however, these were non-significant. In addition to lacking precision, both studies highlighted a potential floor effect of low anger ratings during the 7-day baseline period, due to the highly supervised secure setting, thus rendering post-treatment improvement difficult to demonstrate within the 7-day post-treatment period.

The two NRCTs (7 & 13) offered similarly positive overall findings, albeit of reduced value due to their "moderate" quality ratings. Study 7 found no significant pre- to post-treatment difference between the EG and CG on the validated self-reported anger measure, although a 30% improvement in EG scores was noted from baseline to post-treatment, whereas CG scores over this period were static. Furthermore, participants' anger diary ratings showed significant between-groups difference post-treatment with large effect sizes. Insufficient CG data was collected to facilitate follow-up comparisons; however, statistically significant improvement was found for self-rated EG anger from pre-treatment to the nine month follow-up period assessed, and for staff-rated anger pre- to 15-month follow-up, both with medium effect sizes. The inconsistency within this study's findings may reflect its "weak" quality, with significant age and gender difference between the unmatched groups, a clear lack of measurement precision reflected in the wide CI [-12.85, -0.09] and the study being underpowered. The second NRCT (13) found significant differences between their EG and CG on three of the four self-report measure subscales. The authors suggest the non-

significant finding reflects limited statistical power, which may be supported by the medium-large effect sizes that were obtained and not adjusted for during analysis. Both NRCTs found a significant improvement in scores obtained for the CG once they had completed treatment, suggesting treatment was responsible for improvements in self-reported anger.

All remaining anger-focussed studies were pre-post case series. Two (1, 6) provided only descriptive data, contributing towards their "weak" quality rating. Both noted overall improvements post-treatment in participants' self-reported anger, maintained or further improved at 15-months follow-up. For study 6, these findings were further supported by reductions in staff-ratings of participant anger maintained at follow-up; study 1 did not collect staff-report data.

The final studies (3, 5, 14) did calculate inferential statistics, but demonstrated contrasting outcomes. Two of the three participants' self-reported anger improvements in study 3 were significant pre- to post-treatment; however, small effect sizes were calculated and the study was insufficiently powered to detect change. Study 5 found no significant effect on anger scores pre-post treatment; however, all participants scored below the mean of the AI-MRP measure utilised, suggesting none had clinically significant anger difficulties prior to intervention. Using the AI-MRP means as normative data, participants' anger scores did reduce from the 13th to 6th percentile pre-post treatment, indicating treatment gains. Conversely, statistically significant improvements were found across all self-report measures in study 14, maintained at 12-month follow-up, and corroborated by statistically significant staff-rated outcomes. The adequately powered medium-large and large effects sizes reported are bolstered by this study's use of the largest sample of all reviewed (n=83).

3.3.2 Changes in aggression

Ten studies (2, 4, 8, 9b, 10, 15) assessed reductions in aggression following treatment. All were pre-post case series with no control or comparison groups, and with the exception of

study 2, employed a multiple baseline comparison period. Half were CBT interventions, with all but one (9b) delivered in a group format.

3.3.2.1 CBT interventions

As noted, studies 1 and 6 were conducted by the same research group and rated "weak" in quality. They were, however, the only interventions to utilise recidivism data as a measure of aggression. Both highlighted no aggressive incidents or violent convictions for participants in the time following referral to treatment, which ranged from 2-10 years at the point of publication. Incident reports can underestimate the prevalence of aggressive behaviour (Larkin, Sylvester, & Jones, 1988); however, these studies emphasise the close monitoring of participants and confidence in the identification of incidents.

Statistically significant reductions in self- and/or staff-rated aggression pre- to post-CBT were also found. For study 3, this decrease was noted for only one participant, while the other two participants scored low on aggression throughout treatment and no significant pre-post differences were found. It is of note that the measure was rated by intervention facilitators, thus is a subjective tool that may have introduced bias, and was completed retrospectively for the past week using casenote data. The study does not state by whom casenotes were completed, and no discussion of the accuracy of incident data is made. Inter-rater reliability for one participant was low due to subtle differences in the interpretation and scoring of incidents. The statistically significant findings of studies 5 and 8 were observed across all participants; however, they are not without limitations. Study 5's findings should be considered in the context of their "weak rating", reflecting the lack of reliability and validity data for their outcome measure when used with PWID, and the study's use of normative data from non-ID adolescents. In study 8, staff ratings were consistently lower than participants', indicating the benefit of measuring social desirability responding.

Statistically significant reductions in aggressive behaviours were found by the CBT studies analysing incident data (8, 9b) with medium-large effect sizes, and gains maintained at study 9b's 12-month follow-up period. In study 8, incidents of verbal aggression increased with a small effect size reported; however, this should be viewed with caution given the wide CI [-24.01, 32.91] indicating the study was underpowered. Incident data were collected by both studies according to operationally-defined categories and 100% inter-rater reliability reported. Study 9b further reduced potential bias with data collected by independent assistants, and categorisation uncertainties resolved through anonymous discussion. Despite these overall robust processes, the absence of CGs impedes firm conclusions on effectiveness.

3.3.2.2 DBT intervention

Statistically significant reductions in aggression were found in study 2 and maintained over the four years that participants were in treatment. The majority of reductions occurred in the first year; however, physical violence reduced more gradually. Incident data were categorised using coding rules by direct-care staff; however inter-rater reliability was not evaluated and the accuracy and objectivity of data is questionable. The lack of CG and lengthy treatment duration further prohibit conclusions on whether the intervention was responsible for aggression reduction or remission may have otherwise occurred over time.

3.3.2.3 Mindfulness interventions

Study 4 found significant reductions in the use of staff observation, physical intervention and seclusion from pre to post-completion of a ward-based mindfulness group. This reduction is suggested to reflect fewer incidents of participant aggression, hence the reduced need for formal staff responses. The study acknowledges that, especially with inter-rater reliability not evaluated and in the absence of a CG, the reduction in staff responses to aggression cannot be causally linked to the intervention. Furthermore, attendance of several

participants was low due to the group's voluntary nature; however, some still achieved a decrease in incidents. This was considered unrelated to the intervention and perhaps associated with the care pathway participant were on to reduce the need for staff responses.

A second, individually-delivered, mindfulness study (10) reported the elimination of physical aggression from pre- to post-treatment, with no such incidents for at least six months prior to intervention end. Verbal aggression was not eliminated but reduced substantially. Incident data were collected by direct-care staff and a mean inter-rater agreement of 92% achieved.

3.3.2.4 BST intervention

The three participants in study 15 all demonstrated significant decreased aggression pre- to post-intervention, occurring with novel antecedents and generalisable outside of treatment. Strategies were employed to improve reliability and validity, including postponing baseline data collection until 90% inter-rater agreement was sustained; with subsequent treatment rating achieving 100% agreement. Treatment integrity was operationalised and measured, aggression baselines carefully conceived to ensure accuracy and detection, and antecedents and consequences consistently presented to ensure aggression reductions were treatment-related. However, the lack of follow-up precludes knowledge of whether gains were maintained post-treatment.

3.3.3 Association between aggression and anger

Study 9a was the only intervention to examine association, with the significant self- and staff-reported aggression reduction (odds ratio 2.57, CI [1.12, 5.90]) found to be significantly associated with improvements in anger over the course of treatment. Of particular note is the statistically significant relationship between aggression reduction and the NAS Total, which previous research highlights as the greatest predictor of inpatient assaultive behaviour (see Novaco & Taylor, 2015), and the STAXI Anger-Out and NAS

Behavioural; the subscales most germane to aggression. A limitation, pertinent to all the case series reviewed, is this study's lack of control or comparison group.

4. Discussion

This review has synthesised the current research pertaining to the effectiveness of psychological treatments for PFID in addressing anger and aggression, and goes beyond previous reviews by considering the value of anger interventions in reducing aggressive behaviour.

In respect of interventions targeting anger, the comparable findings across studies of similar quality currently suggest that longer or more intense interventions do not appear necessary for improvements to occur. Individual and group CBT interventions also produced similar outcomes, as has been observed in past research (Nicoll et al., 2013; Rose, O'Brien, & Rose, 2009). Overall, there is some evidence for the short-term effectiveness of these interventions, with all studies obtaining either statistically significant improvement or outcomes in the desired direction. However, methodological flaws were highlighted through appraisal and all anger interventions subsequently deemed of weak-moderate quality.

Seven of the nine studies originate from two research groups, potentially impacting generalisability. Of the five studies reporting statistically significant results, only one was adequately powered to detect with any precision the medium-large effect sizes obtained. The remainder, whether achieving significance or not, all had small samples with no reported use of a power calculation to determine size, and suffered a lack of statistical power and wide CIs, rendering their findings equivocal. Two studies provided descriptive data only, and while adding to the positive trend of results and furthering knowledge of anger interventions for PFID, no conclusions on effectiveness can be drawn.

A significant limitation identified by the review was the reference made by only four studies (1, 11-13) to their samples as having clinically significant anger difficulties prior to

treatment. Therefore, improvements in other samples may not have been captured by the outcome measures. The lack of reported clinically significant anger may add weight to the previous finding that PFID do not have higher levels of anger than their community-based peers (Nicoll & Beail, 2013) or more simply highlight poor reporting practices. It is of interest that the one study (5) that stated participants did not have clinically significant anger difficulties pre-treatment did observe statistically significant reductions in aggression. This may reflect the acknowledgment within the literature that aggression does not require anger, and also rejects Nicoll and Beail's assertion that anger interventions will not reduce aggression in PFID who do not have high levels of anger.

Overall, the results suggest anger-focussed interventions for PFID, specifically CBT-based treatment, are feasible and can offer short-term anger improvement; however, methodological issues preclude firm conclusion on effectiveness. No inference can be made regarding long-term effectiveness as follow-up data for both EG and CGs was obtained by only one of the trials for a period of four months, and by only three of the single-group interventions; two of which were the descriptive studies.

Turning to treatments targeting aggression, there was some heterogeneity in duration and mode (i.e., individual or group-based; CBT, mindfulness, DBT or BST); however, no format produced noticeably better outcomes over another. Three studies, all delivering CBT, reported mixed outcomes on participant and staff-rated aggression, although these findings are questionable. The first study's measure was not validated for PWID and participants did not display clinically significant aggression prior to treatment. The measure utilised by the second study was completed by potentially biased facilitators, while the intervention was not adapted for PWID. The final study's findings indicated social desirability responding; however, this was the only intervention to validate responses against actual behaviour and found statistically significant reductions on all forms except verbal aggression.

The remaining interventions employed "socially validated" (Lindsay & Hastings, 2004) outcomes of violent recidivism and aggressive incidents. Reoffending data was provided by the two descriptive CBT studies, who reported zero recidivism with relatively long follow-up periods of 2-10 years. Those studies that alternatively collected incident data all reported statistically significant reductions in incidents, with medium-large effect sizes. All employed robust incident data collection processes, thus it can be argued that the findings relating to reduced post-treatment aggression are the most salient within this review. However, all suffered limited statistical power as discussed, and none had comparison groups, preventing conclusive attribution of gains solely to treatment. Only one study mentioned clinical significance but again did not comment on how this was established, while the majority did not provide follow-up data, precluding consideration of the long-term effectiveness of aggression interventions for PFID.

The one study (9a) to assess association found a statistically significant relationship between reductions in aggression and improved anger ratings. This study provides promising evidence for the effectiveness of interventions for PFID targeting anger in reducing aggression. However, in addition to the lack of comparison group limiting firm conclusion on effectiveness is consideration of anger and aggression as situationally triggered and the potential confounders of positive staff responding or other reductions in antecedents.

In summary, the findings are consistent with systematic and meta-analytic reviews of anger and/or aggression interventions for PWID in non-forensic settings (Ali et al., 2015; Borsay, 2013; Hamelin et al., 2013; Nicoll et al., 2013; Vereenooghe & Langdon, 2013): Evidence offers support for their effectiveness; however, methodological shortcomings—namely related to small samples and a lack of controlled confounders, follow-up periods, and comparison groups—indicate results should be interpreted with caution and limit generalisable conclusions.

4.1 Limitations of the review

The reporting quality of the current review met in full the PRISMA (Moher et al., 2009) and STROBE cross-sectional study guidelines (von Elm et al., 2008). Despite this, limitations remain. A single reviewer searched and selected papers, therefore, reliability was not cross-checked. However, it is unlikely large-scale studies were missed. The review of articles published only in English language may have further neglected relevant research and be considered a source of bias.

Furthermore, tools such as the EPHPP are subjective and can lead to underestimation of quality. For example, journal-enforced word count limitations may account for the failure of studies to document certain procedures, and non-reporting does not confirm omission (Soares et al., 2004); however, a number of studies received "weak" ratings due absences of information assessed by the EPHPP. Moreover, while the EPHPP is designed for use against all quantitative designs, it includes factors that were less applicable to the studies reviewed. Modifications were made to address the "hierarchy of evidence" that favours RCTs, while "unclear" or "weak" ratings of blinding did not reduce the global score achieved by any study. It may have been useful to appraise the CTs and case series studies separately, with the latter scored against a more specific tool such as the Newcastle Ottawa Scale (Wells et al., 2011). Nonetheless, the independent scoring of a proportion of the studies is hoped to have controlled for subjective bias, and the EPHPP provided important insights on confounding variables and attrition, which were useful during analysis.

4.2 Future research

While the feasibility of RCTs with PWID has been demonstrated (e.g., Hassiotis et al., 2013), concerns pertinent to forensic settings remain around informed consent and the ethics and validity of control groups (Erlen et al., 2015). Other ecologically-valid research designs can provide the strong evidence base required by delivering clearly-defined

interventions with adequately powered sample sizes; reporting of clinical levels of pre- and post-treatment anger levels; carefully designed baselines to ensure detection of treatment effects; and consideration of confounders such as social desirability and changes to pre- and post-treatment antecedents.

Follow-up periods of longer duration are necessary to explore whether treatment gains are maintained, especially given the concerns of PWID that progress made in therapy may not be maintained beyond discharge (Pert et al., 2013). This is of particular importance in forensic settings where "successful" completion of anger and aggression interventions may dictate an individual's reintegration back into the community, where continued desistance is required to prevent readmission. Longitudinal studies with recidivism data would further provide insight into the influence of forensic settings and whether skill-use is motivated by release rather than interpersonal change. Such studies should also report on implementation costs versus treatment-as-usual so that service commissioners can recognise the cost, as well as clinical, effectiveness of these interventions.

Of vital importance is the explicit documentation of how interventions are adapted to improve engagement, comprehension and outcomes to provide replicable evidence for the effectiveness of anger and aggression interventions for PFID. Furthermore, measures of acquisition would contribute towards ensuring participants understand and thus able to apply target skills. Finally, component studies and qualitative exploration of mechanisms for change, therapeutic process and engagement would offer valuable understanding of what impedes or facilitates effectiveness of anger and aggression interventions for this population (Jahoda, Dagnan, Stenfert Kroese, Pert, & Trower, 2009).

4.3 Clinical implications

Current evidence-based practice guidance for anger and aggression in PWID constitutes two sentences within the NICE guideline on challenging behaviour (NICE, 2015).

This recommends "interventions for adults with an anger management problem…should be based on cognitive-behavioural principles and delivered individually or in groups over 15–20 hours" (p. 31). This document was not developed with consideration of PFID and, therefore, its brief guidance in respect of anger is unlikely to meet the potentially differing personal and environmental needs and challenges of this population. Although the current review does not reject the NICE recommendation of CBT, it also cannot offer support, while it is of further note that the shortest duration of the CBT studies reviewed spanned 48-hours with this intervention also not having been adapted for PWID.

Forensic ID services and practitioners must, therefore, rely heavily on published studies such as those reviewed, along with professional judgement, when deciding how best to work in this area. Those receiving treatment within forensic ID settings tend to be placed far from home and their support network, and their detention is costly; yet often prolonged due to the threshold of risk reduction required for release (Davoren et al., 2015). Therefore, and particularly within the current climate of austerity, the main focus of interest for commissioners and social policy makers are interventions that will reduce recidivism (Lindsay & Beail, 2004) while being cost-effective. It is paramount that evidence-based interventions for anger and aggression difficulties for PFID are easily identifiable. While the review offers no firm conclusion in respect of clinical effectiveness and was unable to discuss implementation cost, it does suggest the utility of psychological interventions for addressing anger and aggression, which although relatively resource-intensive are preferable to reliance on psychopharmacology and its significant side-effects (Willner, 2015). Through synthesis and appraisal, the review provides a more accessible and objective foundation for informed decision-making, and calls for practitioners to disseminate their implementation of anger and aggression interventions for PFID, adhering to the recommendations made and reporting on costs, to develop clinical practice.

4.4 Conclusion

The review is the first to systematically examine psychological treatment for PFID targeting anger and aggression. The results highlight an emerging evidence base for the utility of interventions in this area; however, are interpreted with caution given the methodological flaws of the studies reviewed. While firm conclusions are currently prohibited, the review provides important considerations both for the design of future interventions and for service providers and clinicians working with PFID. Further research is warranted, focussing on improving the quality and generalisability of findings in respect of effectiveness.

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Tables and Figures

Figure A.1: Systematic search process depicted using PRISMA flow diagram template

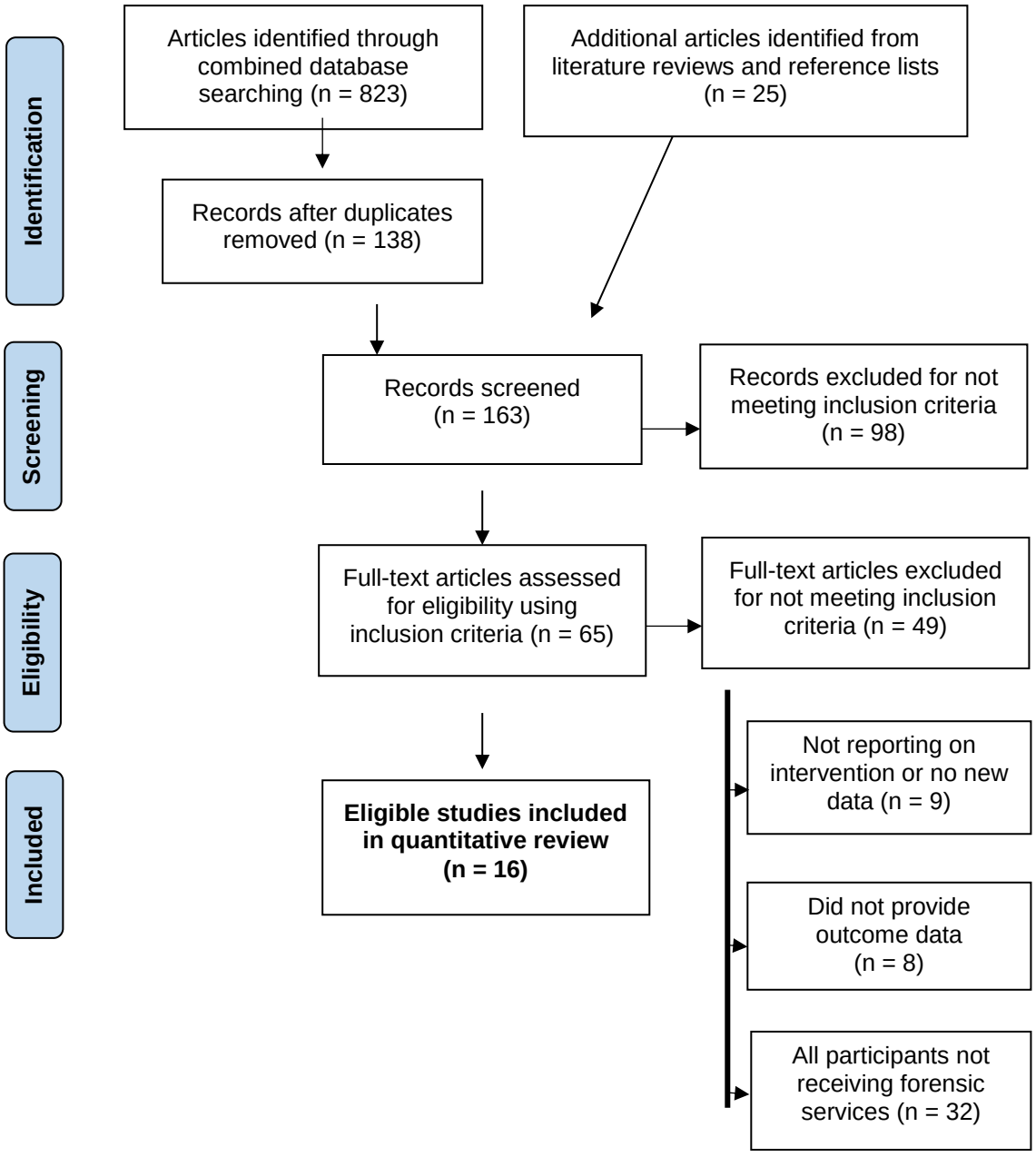

Fig. A.1. PRISMA flow diagram of systematic search process.

Table A.1. Free text search set terms

1st search set	2nd search set	3rd search set
"learning disab*",	"forensic",	"intervention",
"intellectual disab*",	"secure",	"therapy",
"intellectual handicap",	"offend*"	"management",
"mental defic*",		"treatment"
"mental handicap",		
"mental retardation"		
"developmental disab*"		

Table A.2. Relevant characteristics and findings of included studies on anger and aggression interventions adapted for PFID

Authors, year, country	Design	Setting	N	Sample demographics	Intervention type and duration	Anger measure	Aggression measure	Outcomes	Follow up
1. Allen, Lindsay, MacLeod, & Smith (2001) UK	Case series	Outpatient ID forensic mental health service	5	All women Age range 18-44 (M = 26, *SD* = 10.4) WAIS FSIQ range 64-75 (M = 69.2, *SD* = 4.8) Race/ethnicity not reported All involved with CJS All committed violent offence	Group-based, CBT-framework: cognitive reappraisal of anger-provoking situations, cognitive reappraisal of personal arousal and arousal reduction techniques (relaxation). 9 months total duration/approx. 40 weekly sessions lasting 40 to 60 minutes	DPI* (SR)	Recidivism - charges or convictions for aggressive behaviour	Reductions in DPI scores at the end of treatment for all participants	Reductions maintained at 9 & 15 months No recidivism 2.5+ years
2. Brown, Brown, & Dibiasio (2013) USA	Longitudinal case series	Outpatient ID forensic mental health service	40	35 men, 5 women Age range 19-63 (M = 30.8, *SD* = 10.1) FSIQ± range 40-95 (M = 60.8, *SD* = 11.5; 82.5% IQ <70) Race/ ethnicity not reported Legal status not reported 88% history of aggression, 45% past arrests for violence	1 hour of individual DBT and 1 hour of DBT Skills System group skills training per week using Linehan's manual Average participant received 82 months of treatment (M = 6.9 years, *SD* = 3.5)	None	3 categories of behavioural incident data: Red Flags (verbal outbursts), Dangerous Situations (threats of violence), and Lapses (actual violence)	Statistically significant reductions in all 3 categories of behaviour over 4 years	None
3. Burns, Bird, Leach, & Higgins (2003) UK	Case series	ID inpatient Medium Secure Unit	3	All men Age range 33–37 (M = 35.5, *SD* = 2.1) 2 Mild and 1 Borderline ID range (FSIQ± not reported) Race/ethnicity not reported All detained under civil and 2 also under criminal MHA Sections Index offences of arson and indecent assault	Group-based manualised CBT: anger psychoeducation, cognitive reappraisal and self-management skills 12 week total duration of 2 sessions per week lasting a total of 2 hours 30 minutes	NAS (SR) STAXI-2 (SR)	MOAS (completed by group facilitators)	Case 1 – mixed improvement Case 2 – mixed improvement Case 3 - increase in anger scores (small effect size)	None
4. Chilvers, Thomas, & Stanbury (2011) UK	Case series	ID inpatient Medium Secure Unit	15	All women Age range 18-47 (M = 30; ¶) 11 Mild and 4 Moderate ID (FSIQ± not reported) Race/ethnicity not reported 7 under civil and 8 under criminal MHA Sections Forensic/aggression history not reported	Open (optional attendance) mindfulness group 6 month total duration of 1-2 group sessions per week lasting 30 minute	None	Data on incidents leading to (a) staff observations, (b) physical intervention by staff, and (c) seclusion	Reductions in the use of (a) observations, (b) physical intervention, and (c) seclusion (medium-large effect sizes)	None

Authors, year, country	Design	Setting	N	Sample demographics	Intervention type and duration	Anger measure	Aggression measure	Outcomes	Follow up
5. Langdon, Murphy, Clare, Palmer, & Rees (2013) UK	Case series	ID inpatient Medium Secure Unit	7	All men Age range 21-36 (M = 28.1, *SD* = 5.6) FSIQ± range 65-111 (M = 78.9, *SD* = 16.4) 3 Mild ID and 4 Asperger's Race/ethnicity not reported All detained under criminal MHA Sections All had previous or index convictions for violence	Manualised CBT 'EQUIP' group - psychoeducation, distortion challenging & strategies, including relaxation; social skills & social decision-making training. 12-week total duration, 4 sessions per week lasting 1 hour	AI-MRP (SR)	HIT (self report)	No significant reduction in anger scores, significantly lower scores on physical aggression HIT subscale	None
6. Lindsay, Allan, MacLeod, Smart, & Smith (2003) UK	Longitudinal case series	Outpatient ID forensic mental health service	6	All men Age range 18-42 (M = 28.3, *SD* = 10.7) WAIS-R FSIQ range 64-70 (M = 67.3, *SD* = 2.3) Race/ethnicity not reported All serving Probation sentences All had convictions for violence	Group-based, CBT framework: behavioural relaxation, stress inoculation, group discussions about anger responses, and role-plays 9 months total duration/approx. 40 weekly sessions lasting 40 to 60 minutes	DPI* (SR) Daily anger diary (SR) Anger-provoking role-plays	Recidivism - charges or convictions for aggressive behaviour	Reduction on DPI scores and diary reports of anger Reduction in aggressive responses	Reductions maintained at 9 & 15 months No recidivism 4+ years
7. Lindsay, Allan, Parry, MacLeod, Cottrell, Overend, & Smith (2004) UK	Controlled trial 1 EG, 1 CG	Outpatient ID mental health service receiving Court and community referrals for aggression	EG: 33 CG: 14	33 men (EG = 75%, CG = 57.15%) 14 women (EG = 25%, CG = 42.85%) EG age§ (M = 28.4; ¶) CG age§ (M = 23.9; ¶) WAIS-R / WAIS-III FSIQ§ (EG M = 65.4; ¶; CG M = 66.2; ¶) Race/ethnicity not reported Legal status not reported Aggression history not reported	EG: Group-based, CBT framework: behavioural relaxation, stress inoculation, group discussions about anger responses, and role-plays 9 months total duration/ approx. 40 weekly sessions lasting 40 to 60 minutes CG: 6-months, delayed routine care waiting-list	EG & CG: DPI (SR) Daily anger diary (SR) EG: Anger-provoking role-plays	None	Reductions in DPI scores and diary reports for EG (large effect size pre-post treatment, medium effect size pretreatment-follow up), but not for CG Reductions in aggressive responsive for EG (not assessed in CG)	EG DPI reductions maintained at 3, 9 & 15 months EG diary followed up 3 & 9 months – reductions maintained
8. McWilliams, de Terte, Leathem, & Malcolm (2014) New Zealand	Case series	Outpatient forensic mental health & ID service providing secure care	5	3 men, 2 women Age range 17-42 (M = 29; ¶) Mild to moderate ID (FSIQ± not reported) 2 New Zealand Māori descent, 3 New Zealand European descent Most under IDCC&R Act (2003) Most had serious offending histories/ imprisonable index offence	Group based CBT with DBT principles: relaxation, chain analysis, wise mind, arousal reduction & distraction techniques, using Stepping Stones manual 22 weeks total duration of weekly, 2 hour long sessions	None	Modified PACS (SR) Modified PACS (CV) Incident data	Improvements in SR PACS scores No improvement of CV PACS scores Reductions in aggressive incidents (medium-large effect size)	Not all gains maintained at 3 month follow up

Authors, year, country	Design	Setting	N	Sample demographics	Intervention type and duration	Anger measure	Aggression measure	Outcomes	Follow up
9a. Novaco & Taylor (2015) UK	Case series	Inpatient forensic metal health hospital with ID Medium Secure, Low Secure, and rehabilitation Units	50	44 men, 6 women Age§ (M = 30; *SD* = 9.6) WAIS-R / WAIS-III FSIQ§ (M = 68.6; *SD* = 6.7) All Caucasian All detained under civil or criminal MHA Sections 84% previous convictions for or history of violence	Individual, manualised CBT: stress inoculation paradigm: cognitive re-restructuring, arousal reduction and behavioural skills training 6 session preparatory phase then 12 week intervention of 18 once or twice weekly sessions	NAS (MSI) STAXI (MSI) PI (MSI) WARS	Physical assault data	Significant reductions in assaults Reductions on STAXI AO, NAS Total, NAS AR, NAS Behavioural subscales & WARS significantly related to the change in assaults (medium effect size) STAXI TA & PI approached significance STAXI Anger Control not significant	Reductions maintained at 12 months
9b. Taylor, Novaco, & Brown (2016) UK	See 9a	See 9a	See 9a	See 9a	See 9a	None	Incident data on Damage to property; Verbal abuse; Verbal threat to assault; Physical assault	Significant reductions in all incident types (medium-large effect sizes)	Reductions in frequency of incidents maintained during 7–12 month follow-up
10. Singh, Lancioni, Winton, Singh, Adkins, & Singh (2008) USA	Case series	ID forensic inpatient mental health facility	6	All men Age range 23-34 (M = 28.5; *SD* = 5.3) All ID but severity reported only for 1 = Mild ID (FSIQ± not reported) 3 Caucasian, 1 African American 1 White Hispanic, 1 non-White Hispanic Legal status not reported All had violent index offences & high numbers of assaults on staff	Individual, Meditation on the Soles of the Feet mindfulness training 27 months total duration of twice-daily 30 minute practice sessions	None	Incident data (SR & staff report) Use of restraint by medication data Use of physical restraint data Staff or peer injury data	Physical aggression incidents eliminated in final six months Verbal aggression decreased substantially No medication or physical restraint required throughout No staff or peer injuries throughout	None
11. Taylor, Novaco, Gillmer, Robertson, & Thorne (2005) UK	RCT 2 sequential EG cohorts, 1 CG EG in this study are EG & CG from 12. Taylor (2002)	Inpatient forensic metal health hospital with ID Medium Secure, Low Secure, and rehabilitation Units	EG: 16 CG: 20	All men EG age§ (M = 29.4; *SD* = 7.6) CG age§ (M = 29.9; *SD* = 8.6) EG WAIS-R FSIQ§ (M = 67.1; *SD* = 4.5) CG WAIS-R FSIQ§ (M = 70.7; *SD* = 4.0) Race/ethnicity not reported EG: 5 under civil and 11 under criminal MHA Sections CG: 4 under civil and 16 under criminal MHA Sections All had past or current anger control problems or convictions	EG: Individual, manualised CBT: stress inoculation, relaxation training, roleplay, cognitive restructuring and psychoeducation 6 session preparatory phase then 12 week intervention of 18 once or twice weekly sessions CG: routine care delayed waiting-list	NAS (SR) STAXI AX (SR) PI (SR) WARS	None	Greater reductions made on all measures by EG; however, only statistically significant Reductions (medium effect size) on NAS Total & Arousal subscale and 1 index of the PI	Further reductions on WARS at 4 month follow up

Authors, year, country	Design	Setting	N	Sample demographics	Intervention type and duration	Anger measure	Aggression measure	Outcomes	Follow up
12. Taylor, Novaco, Gillmer, & Thorne (2002) UK	RCT 1 EG, 1 CG	Inpatient forensic metal health hospital with ID Medium Secure, Low Secure, and rehabilitation Units	EG: 9 CG: 10	All men EG age§ (M = 29; *SD* = 5.5)) CG age§ (M = 29.3; *SD* = 8.8) EG WAIS-R FSIQ§ (M = 69.3; *SD* = 3.7) CG WAIS-R FSIQ§ (M = 66.7; *SD* = 5.2) Race/ethnicity not reported EG: 2 under civil and 7 under criminal MHA Sections CG: 3 under civil and 7 under criminal MHA Sections All had past or current anger control problems or convictions	EG: Individual, manualised CBT: relaxation training, roleplay, cognitive restructuring and psychoeducation 6 session preparatory phase then 12 week intervention of 18 one-hour long, twice weekly sessions CG: routine care delayed waiting-list	EG & CG: PI (SR) WARS	None	Reduction in PI scores for EG, increase in PI score for CG (large effect size) Reductions in WARS ratings for EG, increase for CG	Improvements maintained to one month follow-up
13. Taylor, Novaco, Guinan, & Street (2004) UK	Controlled trial 1 EG, 1 CG	Inpatient forensic metal health hospital with ID Medium Secure, Low Secure, and rehabilitation Units	EG: 9 CG: 8	All men EG age§ (M = 29; *SD* = 5.5) CG age§ (M = 29.4; *SD* = 9.6) EG WAIS-R FSIQ§ (M = 69.3; *SD* = 4.2) CG WAIS-R FSIQ§ (M = 66.4; *SD* = 6.2) Race/ethnicity not reported EG: 2 under civil and 7 under criminal MHA Sections CG: 2 under civil and 6 under criminal MHA Sections All had past or current anger control problems or convictions	Individual, manualised CBT: relaxation training, roleplay, cognitive restructuring and psychoeducation 6 session preparatory phase then 12 week intervention of 18 one-hour long, twice weekly sessions CG: routine care delayed waiting-list	IPT	None	IPT indices significantly lower in EG compared to CG (medium-large effect size)	None
14. Taylor, Novaco, & Johnson (2009) UK	Case series	Inpatient forensic metal health hospital with ID Medium and Low Secure, and rehabilitation Units	83	67 men, 16 women Age range 19-62 (M = 32.4; *SD* = 10.9) WAIS-III FSIQ (M = 68.4; *SD* = 5.7) Race/ethnicity not reported All detained under MHA & past or current anger/aggression issues	Individual, manualised CBT: stress inoculation, relaxation training, roleplay, cognitive restructuring and psychoeducation 6 session preparatory phase then 12 week intervention of 18 twice weekly sessions	NAS (SR) STAXI TA & AX (SR) PI (SR) WARS	None	Significant improvements on all measures (medium-large and large effect sizes)	Significant improvements maintained at 12 month follow up
15. Travis & Sturmey (2013) USA	Case series	Inpatient locked ID forensic facility	3	All men Age range 32-46 (M= 39; *SD* = 7) FSIQ± range 58-63 (M = 60.6; *SD* = 2.5) Race/ethnicity not reported Legal status not reported All had histories of criminal charges and current aggression problems	Individual behavioural skills training for target and replacement responses utilising staff modelling, a token economy system and positive reinforcement. 1 hour observations, 3 per day every other day over 3 weeks	None	Observation data	Reduction in aggressive responses and increase in replacement responses	None

Note. ± = IQ assessment tool not stated; ¶ = *SD* not reported and insufficient information provided to calculate; § = range not reported; AI-MRP = Anger Inventory for Mentally Retarded Persons (Benson, 1992); AX = Anger Expression subscale; AO = Anger Out subscale; AR = Anger Regulation subscale; CBT = Cognitive Behavioural Therapy; CG = control group; CJS = Criminal Justice System; CV = carer version; DBT = Dialectical Behaviour Therapy; DPI = Dundee Provocation Inventory (Alder & Lindsay, 2007); EG = experimental group; EQUIP = Equipping Youth to Help One Another programme; HIT = How I Think questionnaire (Barriga, Gibbs, Potter, & Liau, 2001); IDCC&R = Intellectual Disability Compulsory Care and Rehabilitation Act (2003); IPT = Imaginal Provocation Test (Taylor, Novaco, Guinan, & Street, 2004); IQ = Intellectual Quotient; MHA = England & Wales Mental Health Act (1983; 2007); MOAS = Modified Overt Aggression Scale (Kay, Wolkenfield, & Murrill, 1988); MSI = Modified to structured interview instead of self-report questionnaire; NAS = Novaco Anger Scale (Novaco, 1994); PACS = Profile of Anger Coping Skills (Willner, Brace, & Phillips, 2005); PI = Provocation Inventory (Novaco, 2003); SR = self-reported; STAXI = State-Trait Anger Expression Inventory (Spielberger, 1996, 1999); TA = Trait Anger subscale; WARS= Ward Anger Rating Scale (Novaco, 1994)
* The studies refer to their use of an “anger inventory” with no citation; clarification sought from one of the authors confirmed that this inventory was the DPI.

Table A.3: Quality appraisal scores for included studies using EPHPP tool

Name of study	Selection bias	Study design	Confounders	Blinding	Data collection	Withdrawals and dropouts	Global quality rating
1. Allen et al. (2001)	Weak	Moderate	Weak	Unclear	Moderate	Moderate	**Weak**
2. Brown et al.(2013)*	Moderate	Moderate	Weak	Unclear	Weak	Moderate	**Weak**
3. Burns et al. (2003)	Moderate	Moderate	Weak	Unclear	Moderate	Moderate	**Moderate**
4. Chilvers et al. (2011)	Moderate	Moderate	Weak	Unclear	Weak	Weak	**Weak**
5. Langdon et al. (2011)	Moderate	Moderate	Weak	Unclear	Weak	Moderate	**Weak**
6. Lindsay et al. (2003)	Moderate	Moderate	Weak	Unclear	Strong	Weak	**Weak**
7. Lindsay et al. (2004)	Weak	Moderate	Weak	Moderate	Strong	Weak	**Weak**
8. McWilliams et al. (2014)	Moderate	Moderate	Weak	Unclear	Moderate	Moderate	**Moderate**
9a. Novaco & Taylor (2015)*	Moderate	Moderate	Moderate	Unclear	Strong	Strong	**Moderate**
9b. Taylor et al. (2016)*	Moderate	Moderate	Moderate	Unclear	Moderate	Strong	**Moderate**
10. Singh et al. (2008)*	Moderate	Moderate	Weak	Unclear	Moderate	Moderate	**Moderate**
11. Taylor et al. (2005)*	Moderate	Moderate	Strong	Weak	Strong	Strong	**Moderate**
12. Taylor et al. (2002)*	Moderate	Moderate	Strong	Weak	Strong	Strong	**Moderate**
13. Taylor et al. (2004)*	Moderate	Moderate	Strong	Weak	Strong	Strong	**Moderate**
14. Taylor et al. (2009)*	Moderate	Moderate	Weak	Unclear	Strong	Weak	**Moderate**
15. Travis & Sturmey (2013)	Weak	Moderate	Moderate	Unclear	Moderate	Moderate	**Moderate**

Note. • = research team includes vested researcher.

Appendices

Appendix A: Quality assessment tool for quantitative studies

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

EPHPP
Effective Public Health Practice Project

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

1 Very likely
2 Somewhat likely
3 Not likely
4 Can't tell

(Q2) What percentage of selected individuals agreed to participate?

1 80-100% agreement
2 60–79% agreement
3 less than 60% agreement
4 Not applicable
5 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

1 Randomized controlled trial
2 Controlled clinical trial
3 Cohort analytic (two group pre + post)
4 Case-control
5 Cohort (one group pre + post (before and after))
6 Interrupted time series
7 Other specify
8 Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

1 Yes
2 No
3 Can't tell

The following are examples of confounders:

1 Race
2 Sex
3 Marital status/family
4 Age
5 SES (income or class)
6 Education
7 Health status
8 Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

1 80 – 100% (most)
2 60 – 79% (some)
3 Less than 60% (few or none)
4 Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

1 Yes
2 No
3 Can't tell

(Q2) Were the study participants aware of the research question?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

1 Yes
2 No
3 Can't tell

(Q2) Were data collection tools shown to be reliable?

1 Yes
2 No
3 Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

1 Yes
2 No
3 Can't tell
4 Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell
5 Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG	MODERATE	WEAK	
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

1 80 -100%
2 60 - 79%
3 less than 60%
4 Can't tell

(Q2) Was the consistency of the intervention measured?

1 Yes
2 No
3 Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

4 Yes
5 No
6 Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

1 Yes
2 No
3 Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

1 Yes
2 No
3 Can't tell

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section.

A	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**	
		1	2	3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1	STRONG	(no WEAK ratings)
2	MODERATE	(one WEAK rating)
3	WEAK	(two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1 Oversight
2 Differences in interpretation of criteria
3 Differences in interpretation of study

Final decision of both reviewers (circle one):

1 STRONG
2 MODERATE
3 WEAK

EFFECTIVE PUBLIC HEALTH PRACTICE PROJECT (EPHPP)

Quality Assessment Tool for Quantitative Studies Dictionary

The purpose of this dictionary is to describe items in the tool thereby assisting raters to score study quality. Due to under-reporting or lack of clarity in the primary study, raters will need to make judgements about the extent that bias may be present. When making judgements about each component, raters should form their opinion based upon information contained in the study rather than making inferences about what the authors intended.

A) SELECTION BIAS

(Q1) Participants are more likely to be representative of the target population if they are randomly selected from a comprehensive list of individuals in the target population (score very likely). They may not be representative if they are referred from a source (e.g. clinic) in a systematic manner (score somewhat likely) or self-referred (score not likely).

(Q2) Refers to the % of subjects in the control and intervention groups that agreed to participate in the study before they were assigned to intervention or control groups.

B) STUDY DESIGN

In this section, raters assess the likelihood of bias due to the allocation process in an experimental study. For observational studies, raters assess the extent that assessments of exposure and outcome are likely to be independent. Generally, the type of design is a good indicator of the extent of bias. In stronger designs, an equivalent control group is present and the allocation process is such that the investigators are unable to predict the sequence.

Randomized Controlled Trial (RCT)
An experimental design where investigators randomly allocate eligible people to an intervention or control group. A rater should describe a study as an RCT if the randomization sequence allows each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. If the investigators do not describe the allocation process and only use the words 'random' or 'randomly', the study is described as a controlled clinical trial.

See below for more details.

Was the study described as randomized?

Score YES, if the authors used words such as random allocation, randomly assigned, and random assignment.

Score NO, if no mention of randomization is made.

Was the method of randomization described?

Score YES, if the authors describe any method used to generate a random allocation sequence.

Score NO, if the authors do not describe the allocation method or describe methods of allocation such as alternation, case record numbers, dates of birth, day of the week, and any allocation procedure that is entirely transparent before assignment, such as an open list of random numbers of assignments. If NO is scored, then the study is a controlled clinical trial.

Was the method appropriate?

Score YES, if the randomization sequence allowed each study participant to have the same chance of receiving each intervention and the investigators could not predict which intervention was next. Examples of appropriate approaches include assignment of subjects by a central office unaware of subject characteristics, or sequentially numbered, sealed, opaque envelopes.

Score NO, if the randomization sequence is open to the individuals responsible for recruiting and allocating participants or providing the intervention, since those individuals can influence the allocation process, either knowingly or unknowingly.

If NO is scored, then the study is a controlled clinical trial.

Controlled Clinical Trial (CCT) An experimental study design where the method of allocating study subjects to intervention or control groups is open to individuals responsible for recruiting subjects or providing the intervention. The method of allocation is transparent before assignment, e.g. an open list of random numbers or allocation by date of birth, etc.

Cohort analytic (two group pre and post) An observational study design where groups are assembled according to whether or not exposure to the intervention has occurred. Exposure to the intervention is not under the control of the investigators. Study groups might be non-equivalent or not comparable on some feature that affects outcome.

Case control study A retrospective study design where the investigators gather ‘cases’ of people who already have the outcome of interest and ‘controls’ who do not. Both groups are then questioned or their records examined about whether they received the intervention exposure of interest.

Cohort (one group pre + post (before and after) The same group is pretested, given an intervention, and tested immediately after the intervention. The intervention group, by means of the pretest, act as their own control group.

Interrupted time series A time series consists of multiple observations over time. Observations can be on the same units (e.g. individuals over time) or on different but similar units (e.g. student achievement scores for particular grade and school). Interrupted time series analysis requires knowing the specific point in the series when an intervention occurred.

C) CONFOUNDERS

By definition, a confounder is a variable that is associated with the intervention or exposure and causally related to the outcome of interest. Even in a robust study design, groups may not be balanced with respect to important variables prior to the intervention. The authors should indicate if confounders were controlled in the design (by stratification or matching) or in the analysis. If the allocation to intervention and control groups is randomized, the authors must report that the groups were balanced at baseline with respect to confounders (either in the text or a table).

D) BLINDING

(Q1) Assessors should be described as blinded to which participants were in the control and intervention groups. The purpose of blinding the outcome assessors (who might also be the care providers) is to protect against detection bias.

(Q2) Study participants should not be aware of (i.e. blinded to) the research question. The purpose of blinding the participants is to protect against reporting bias.

E) DATA COLLECTION METHODS

Tools for primary outcome measures must be described as reliable and valid. If 'face' validity or 'content' validity has been demonstrated, this is acceptable. Some sources from which data may be collected are described below:

Self reported data includes data that is collected from participants in the study (e.g. completing a questionnaire, survey, answering questions during an interview, etc.).

Assessment/Screening includes objective data that is retrieved by the researchers. (e.g. observations by investigators).

Medical Records/Vital Statistics refers to the types of formal records used for the extraction of the data.

Reliability and validity can be reported in the study or in a separate study. For example, some standard assessment tools have known reliability and validity.

F) WITHDRAWALS AND DROP-OUTS

Score **YES** if the authors describe BOTH the numbers and reasons for withdrawals and drop-outs. Score **NO** if either the numbers or reasons for withdrawals and drop-outs are not reported. The percentage of participants completing the study refers to the % of subjects remaining in the study at the final data collection period in all groups (i.e. control and intervention groups).

G) INTERVENTION INTEGRITY

The number of participants receiving the intended intervention should be noted (consider both frequency and intensity). For example, the authors may have reported that at least 80 percent of the participants received the complete intervention. The authors should describe a method of measuring if the intervention was provided to all participants the same way. As well, the authors should indicate if subjects received an unintended intervention that may have influenced the outcomes. For example, co-intervention occurs when the study group receives an additional intervention (other than that intended). In this case, it is possible that the effect of the intervention may be over-estimated. Contamination refers to situations where the control group accidentally receives the study intervention. This could result in an under-estimation of the impact of the intervention.

H) ANALYSIS APPROPRIATE TO QUESTION

Was the quantitative analysis appropriate to the research question being asked?

An intention-to-treat analysis is one in which all the participants in a trial are analyzed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis.

Component Ratings of Study:

For each of the six components A – F, use the following descriptions as a roadmap.

A) SELECTION BIAS

Strong: The selected individuals are very likely to be representative of the target population (Q1 is 1) **and** there is greater than 80% participation (Q2 is 1).

Moderate: The selected individuals are at least somewhat likely to be representative of the target population (Q1 is 1 or 2); **and** there is 60 - 79% participation (Q2 is 2). 'Moderate' may also be assigned if Q1 is 1 or 2 and Q2 is 5 (can't tell).

Weak: The selected individuals are not likely to be representative of the target population (Q1 is 3); **or** there is less than 60% participation (Q2 is 3) **or** selection is not described (Q1 is 4); and the level of participation is not described (Q2 is 5).

B) DESIGN Strong: will be assigned to those articles that described RCTs and CCTs.

Moderate: will be assigned to those that described a cohort analytic study, a case control study, a cohort design, or an interrupted time series.

Weak: will be assigned to those that used any other method or did not state the method used.

C) CONFOUNDERS Strong: will be assigned to those articles that controlled for at least 80% of relevant confounders (Q1 is 2); **or** (Q2 is 1). **Moderate:** will be given to those studies that controlled for 60 – 79% of relevant confounders (Q1 is 1) **and** (Q2 is 2). **Weak:** will be assigned when less than 60% of relevant confounders were controlled (Q1 is 1) **and** (Q2 is 3)

or

control of confounders was not described (Q1 is 3) **and** (Q2 is 4).

D) BLINDING

Strong: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **and t**he study participants are not aware of the research question (Q2 is 2).

Moderate: The outcome assessor is not aware of the intervention status of participants (Q1 is 2); **or** the study participants are not aware of the research question (Q2 is 2); **or b**linding is not described (Q1 is 3 and Q2 is 3).

Weak: The outcome assessor is aware of the intervention status of participants (Q1 is 1); **and** the study participants are aware of the research question (Q2 is 1).

E) DATA COLLECTION METHODS

Strong: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have been shown to be reliable (Q2 is 1).

Moderate: The data collection tools have been shown to be valid (Q1 is 1); **and** the data collection tools have not been shown to be reliable (Q2 is 2) **or** reliability is not described (Q2 is 3).

Weak: The data collection tools have not been shown to be valid (Q1 is 2) **or** both reliability and validity are not described (Q1 is 3 and Q2 is 3).

F) WITHDRAWALS AND DROP-OUTS - a rating of: Strong: will be assigned when the follow-up rate is 80% or greater (Q2 is 1). **Moderate:** will be assigned when the follow-up rate is 60 – 79% (Q2 is 2) **OR** Q2 is 5 (N/A). **Weak:** will be assigned when a follow-up rate is less than 60% (Q2 is 3) or if the withdrawals and drop-outs were not described (Q2 is 4).

Appendix B: Journal instructions for authors

BEHAVIOUR RESEARCH AND THERAPY

AUTHOR INFORMATION PACK

PREPARATION

Article structure

Subdivision - unnumbered sections

Divide your article into clearly defined sections. Each subsection is given a brief heading. Each heading should appear on its own separate line. Subsections should be used as much as possible when crossreferencing text: refer to the subsection by heading as opposed to simply 'the text'.

Appendices

If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

Essential title page information

• ***Title.*** Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.

• ***Author names and affiliations.*** Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lowercase superscript letter immediately after the author's name and in front of the appropriate address.

Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.

• ***Corresponding author.*** Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. **Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.**

• ***Present/permanent address.*** If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

Abstract

A concise and factual abstract is required with a maximum length of 200 words. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if essential, then cite the author(s) and year(s). Also, non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself.

Graphical abstract

Although a graphical abstract is optional, its use is encouraged as it draws more attention to the online article. The graphical abstract should summarize the contents of the article in a concise, pictorial form designed to capture the attention of a wide readership. Graphical abstracts should be submitted as a separate file in the online

submission system. Image size: Please provide an image with a minimum of 531 × 1328 pixels (h × w) or proportionally more. The image should be readable at a size of 5 × 13 cm using a regular screen resolution of 96 dpi. Preferred file types: TIFF, EPS, PDF or MS Office files. You can view Example Graphical Abstracts on our information site.
Authors can make use of Elsevier's Illustration and Enhancement service to ensure the best presentation of their images and in accordance with all technical requirements: Illustration Service.

Highlights
Highlights are mandatory for this journal. They consist of a short collection of bullet points that convey the core findings of the article and should be submitted in a separate editable file in the online submission system. Please use 'Highlights' in the file name and include 3 to 5 bullet points (maximum 85 characters, including spaces, per bullet point). You can view example Highlights on our information site.

Keywords
Immediately after the abstract, provide a maximum of 6 keywords, to be chosen from the APA list of index descriptors. These keywords will be used for indexing purposes.

Abbreviations
Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in the footnote. Ensure consistency of abbreviations throughout the article.

Acknowledgements
Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

Formatting of funding sources
List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding has been provided for the research, please include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Shorter communications
This option is designed to allow publication of research reports that are not suitable for publication as regular articles. Shorter Communications are appropriate for articles with a specialized focus or of particular didactic value. Manuscripts should be between 3000-5000 words, and must not exceed the upper word limit. This limit includes the abstract, text, and references, but not the title page, tables and figures.

Artwork

Electronic artwork

General points

- Make sure you use uniform lettering and sizing of your original artwork.
- Embed the used fonts if the application provides that option.
- Aim to use the following fonts in your illustrations: Arial, Courier, Times New Roman, Symbol, or use fonts that look similar.
- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
- Provide captions to illustrations separately.
- Size the illustrations close to the desired dimensions of the published version.
- Submit each illustration as a separate file.

A detailed guide on electronic artwork is available.

Tables

Please submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules.

References

Citation in text

Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list they should follow the standard reference style of the journal and should include a substitution of the publication date with either 'Unpublished results' or 'Personal communication'. Citation of a reference as 'in press' implies that the item has been accepted for publication.

Web references

As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.

Reference style

Text: Citations in the text should follow the referencing style used by the American Psychological Association. You are referred to the Publication Manual of the American Psychological Association, Sixth Edition, ISBN 978-1-4338-0561-5, copies of which may be ordered online or APA Order Dept., P.O.B. 2710, Hyattsville, MD 20784, USA or APA, 3 Henrietta Street, London, WC3E 8LU, UK.

List: references should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters 'a', 'b', 'c', etc., placed after the year of publication.

Examples:

Reference to a journal publication:

Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2010). The art of writing a scientific article. *Journal of Scientific Communications, 163*, 51–59.

Reference to a book:

Strunk, W., Jr., & White, E. B. (2000). *The elements of style.* (4th ed.). New York: Longman, (Chapter 4).

Reference to a chapter in an edited book:

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Chapter 2 : Research Paper

Adapting dialectical behaviour therapy in forensic learning disability services: A grounded theory informed study of "what works"

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Abstract

This research aims to generate a service user-informed theory of the process of engagement and perceived change within dialectical behaviour therapy (DBT) for people with intellectual disabilities in forensic settings. Emerging evidence indicates the effectiveness of DBT for this population; however, little is known about "what works" to facilitate engagement and produce change. Nine service user participants across two NHS secure inpatient services were interviewed, and constructivist grounded theory used to develop a data-driven model of the processes involved in DBT. The model provides insights into how change occurs during DBT delivered in forensic settings: Essentially, DBT constitutes a challenging journey, yet provides the motivation and means for individuals to address their intra or interpersonal aggression and progress towards release. Practical suggestions are offered to clinicians for increasing intrinsic motivation and reducing the perceived coercion and distress experienced by people with intellectual disabilities undertaking DBT in forensic services. Recommendations are made for future research to employ longitudinal mixed-method designs to explore, monitor and address these potential aversive elements within psychological interventions for PWID, to enhance treatment experience, effectiveness and evaluation.

Keywords:

Intellectual disabilities

Forensic

Emotion regulation

Dialectical behaviour therapy

Process of change

Qualitative methods

1. Introduction

Dialectical Behaviour Therapy (DBT; Linehan, 1993a; 1993b) is a comprehensive, habilitative and multi-modal psychological treatment that combines cognitive and behavioural principles with dialectic philosophy and the Zen practice of mindfulness. Developed as a specific treatment for persons assigned the diagnosis of Borderline Personality Disorder (BPD), DBT has amassed substantial empirical evidence of improvements in the emotion regulation difficulties often experienced by such individuals, including self-injurious and parasuicidal behaviour, suicidal ideation, low mood, anxiety, substance dependence, and anger and aggression. DBT has also been found to reduce treatment attrition, frequency and duration of rehospitalisation, and overall cost of mental health treatment (Kliem, Kröger, & Kosfelder, 2010; Frazier & Vela, 2014; Panos, Jackson, Hasan, & Panos, 2014; Stoffers et al., 2012).

This empirical support has led to the extended application of DBT to people with a range of mental health difficulties involving problems with emotion regulation (Kring & Sloan, 2009). Consequently, DBT is no longer regarded a BPD-specific treatment, as acknowledged within the recent edition of the DBT skills manual, which encourages and exemplifies its adaptation for various populations and treatment settings (Linehan, 2015).

1.1 DBT for people with intellectual disabilities

1.1.1 Relevance

One specific population regarded as commonly experiencing difficulties with emotion regulation are people with intellectual disabilities (PWID). Such difficulties are considered a core element of the behaviours that PWID can display that challenge services, family members and carers (Black, Cullen, & Novaco, 1997). Challenging behaviour can include aggression towards self, others and property, stereotypic behaviour and withdrawal, and in the UK and North America has been found to be prevalent in 5-15% of PWID in the

community and 30-40% of those in hospital settings (National Institute for Health and Care Excellence, 2015). With many mental health problems regarded as consequences of emotion dysregulation (Roberton, Daffern, & Bucks, 2012), it is of further note that the prevalence of such difficulties in PWID is considered to be at least consistent with rates in the general population (Lindsay et al., 2015), if not greater, with difficulties overshadowed by and misinterpreted as challenging behaviour (Nylander, Fernell, & Gillberg, 2016).

Therefore, with DBT's focus on addressing emotion regulation difficulties, it is perhaps not surprising that DBT has, over the past decade, been introduced as a psychological intervention for PWID. Furthermore, DBT's acceptance-based, empowering and person-centred approach is consistent with values important for working with PWID (Department of Health, 2014), and its behavioural, cognitive and mindfulness techniques are all evidence-based approaches within this population, when specific adaptations are made (Taylor, Lindsay, Hastings, & Hatton, 2013).

1.2.1 Adaptations for PWID

As PWID characteristically experience difficulties with communication and learning, this population has historically been considered unable to engage with and benefit from talking therapies (Bender, 1993). A significant body of evidence, largely from studies of cognitive-behavioural therapy (CBT) for PWID, has emerged to quash this assumption and specify the adaptations of benefit in ensuring mainstream psychological therapies are accessible to and meaningful for PWID (see Beail, 2016; Lindsay, Jahoda, Willner, & Taylor, 2013).

With this population typically having receptive language difficulties, lower levels of literacy and limited information processing abilities (Carr, Linehan, O'Reilly, Walsh, & McEvoy, 2016), the use of jargon-free, simplified language and short sentences containing a single concept are essential if PWID are to understand what is being said to them and

expected of them within therapy (Lindsay, 2009). Therefore, within CBT for PWID, more inductive and experiential methods have been used to illustrate concepts and promote learning, including pictorial and audio stimuli, Socratic questioning, and the use of role play: the latter two being particularly helpful in ascertaining understanding given that PWID are often skilled in masking their deficits in order to be accepted by more-able others (Willner & Lindsay, 2016). PWID also commonly have difficulties in retaining and assimilating new information, thus frequent repetition and recapitulation of skills is necessary to ensure that these can be remembered and implemented outside of the therapy room (Ramsey, 2010). Providing greater flexibility of sessions, and thus further opportunities to be responsive to learning and treatment needs, can also assist in compensating for the executive functioning difficulties of PWID (Roelofs et al., 2015).

Consequently, while DBT's supportive, skills-based approach is appropriate for PWID, its complicated terminology and lengthy mnemonics, large number of target skills to acquire and practice independently, and reliance on handouts and homework requiring high levels of literacy, all pose potential barriers (Dykstra & Charlton, 2003). Suggestions of specific modifications that may promote the comprehension, retention and subsequent application of DBT by PWID have been proposed, with the focus largely on simplifying language used and concepts introduced, reducing the length of sessions, reformatting written materials and utilising audio and visual aids, along with providing additional opportunity for repetition and rehearsal of skills and assistance outside of sessions with homework (Dykstra & Charlton, 2008; Lew, Matta, Tripp-Tebo, & Watts, 2006).

1.3.1 Effectiveness of DBT for PWID

Although these adaptations to DBT for PWID make outcome generalisations difficult, an emerging body of community-based research has shown promising results. Three early case study reports described treatment for PWID and BPD combining pharmacological and

behavioural approaches with some DBT techniques (Esbensen & Benson, 2003; Mavromatis, 2000; Wilson, 2001). These studies observed marked pre-post treatment improvements in aggressive and self-injurious behaviours; however, the data provided precludes any conclusions on the effectiveness of DBT as a standalone intervention.

More recent pre-post case series have delivered full DBT programmes incorporating the adaptations discussed in section 1.2.1 to community samples of PWID, and have reported significant reductions in aggression, risk-taking and self-harm (Brown, Brown, & DiBiasio, 2013; Charlton & Dykstra, 2011; Lew et al., 2006) and the prevention of community placement breakdown (Baillie & Slater, 2014). A recent case study of similarly adapted DBT noted clinically significant post-treatment improvements in self-harm and self-esteem in a participant who completed DBT (McNair, Woodrow, & Hare, 2016). In the one qualitative study located, PWID regarded the programme positively and reported sustained improvements in their behaviour (Hall, Bork, Craven, & Woodrow, 2013).

1.2 DBT for PWID in forensic settings

The promising evidence for DBT adapted for PWID in the community as an effective intervention likely prompted its introduction to forensic ID services. Furthermore, the most prevalent problems reported in the histories or current presentations of people in forensic ID services (PFID)[2] are indicative of emotion dysregulation: largely aggression, followed by sexual offences and substance abuse (Lindsay, Hastings, & Beail, 2013). Higher rates of anxiety, depression and low self-esteem have also been found in this population than in PWID residing in the community (Hogue et al., 2007). This may indicate that those who become involved with forensic services are more disposed, biologically, socially and

[2] Although the terminology *ID offender* is frequently employed within the literature, this paper instead utilises *people in forensic ID services* (PFID) in reference to intellectually disabled adults who are subject to forensic service pathways. This distinction acknowledges that many such individuals have not committed or been convicted of criminal offences but are deemed to have forensic needs due to judgements around the risk of harm they pose to others.

psychologically, to emotion dysregulation. Nonetheless, PFID will remain in such services until they demonstrate increased self-regulation (Kitchen, Thomas, & Chester, 2014).

The first published exploration of DBT for PFID was provided in 2004 by Dunn and Bolton. Their case study of a male with ID located in a UK Medium Secure Unit (MSU) refers to the use of a DBT-informed formulation and highlights significant behavioural improvements. However, as with the early community case studies discussed in section 1.3.1, the actual utilisation of DBT skills and the extent to which these were responsible for change is unclear.

In parallel again with community studies, recent years have seen the application of DBT programmes more akin to that set out by Linehan (1993b) for PFID. In 2010, Sakdalan, Shaw and Collier reported on outcomes of a pilot DBT skills group for five men and one woman with mild to moderate ID, five of whom had previous charges or convictions for violence, and all residing in either ID forensic community accommodation or an MSU in New Zealand. Significant reductions in risk factors and improvements in protective factors and global functioning were measured post-treatment, and non-significant improvements in interpersonal coping skills also observed. Data on incidents of aggression were collected but compromised, precluding conclusions. Qualitative participant feedback was also obtained and included recommendations for further use of visual aids, simplification of handouts and more homework assistance.

In their 2011 paper, Morrisey and Ingamells described the evolution over a six-year period of their adapted group and individual session DBT programme for males with mild ID in a High Security ID service in the UK. Preliminary results indicated significant reductions in overall psychological distress and, in comparisons with a waiting list control group, participants were more likely to progress to conditions of lower security. No significant differences in aggressive incidents were reported; however, baseline rates were generally

low, likely due to the highly supervised and restrictive environment. While participant feedback was not described, the authors comment on how, despite extensive revisions to their adapted DBT programme, there remained an issue in respect of "language and concepts that are too complex for some" (p.15).

Again mirroring the community-based literature, only one published study appears to have employed a qualitative methodology. Following interviews with female ID participants in a UK MSU, Johnson and Thomson (2016) described the importance of building trust within the DBT group and the difficulties experienced with learning and applying skills. Nonetheless, participants regarded their perseverance as worthwhile, in terms of improved self-belief and progression towards lower security conditions. Finally, Verhoeven (2010) and Sakdalan and Collier (2012) described adapted DBT for PFID displaying sexual risk factors and indicated improvements in target behaviours as well as general aggression and self-harm.

These positive preliminary findings indicate that the provision of adapted DBT for this population may be beneficial in reducing behavioural difficulties associated with emotion regulation. This is encouraging given the overall relevance of DBT for PWID as discussed in section 1.1.1, coupled with additional factors, present in the sub-group of PWID who have criminogenic needs, which may further increase the merits of DBT. However, the available literature also highlights the difficulties service users experience with DBT despite varied and extensive adaptations. Furthermore, it has been questioned in respect of mainstream DBT whether its reported efficacy is "derived from specific ingredients of dialectical behaviour therapy'' (American Psychiatric Association, 2001). This understanding is certainly absent within the ID field, given the limited investigations into adapted DBT.

1.3 Study aims

Consequently, this study aims to fill the gap in the current literature by generating a clinically relevant theory, drawn from service user perspectives, of the process of engagement

with a DBT group and how this relates to perceived change. Such focus on the individual's experience is lacking in the existing literature, thus by employing a qualitative methodology the research will start to address this deficit and meet the call for researchers to go beyond global measures when seeking service user feedback (Francis, 2013).

2. Method

2.1 Setting and participants

Three NHS low and/or medium secure ID units in the North, South and Midlands of England agreed to act as research hosts. No participants were recruited from the third site. From the remaining two sites, 12 service users opted into the study; three of whom later withdrew for personal reasons. Consequently, five females and four males participated. The participant inclusion and exclusion criteria can be found in Table A.1. Table A.2 details participants' demographics. The DBT groups attended by participants at both sites were delivered over two six-month blocks by facilitator teams composed of psychologists, nurse therapists, assistant practitioners, and occupational therapists who had all received the same licensed DBT training. The DBT materials utilised within sessions were provided by the training company, yet the content of some handouts was adapted by the individual sites according to their perception of the accessibility needs of their group members.

[INSERT TABLES A.1 & A.2]

2.2 Design

A qualitative design using semi-structured interviews was employed. Constructivist grounded theory (GT; Charmaz, 2014) was the chosen methodology as, consistent with the research aim, it facilitates generation of explanatory theory from data, rather than simply describing personal narratives (Birks & Mills, 2011). Charmaz (2006) posits GT as offering

an interpretive portrayal of the studied world, with participants' data and researchers' resultant GTs considered constructions of reality. This position is compatible with the author's critical realist epistemological position, which acknowledges the "subjective element in knowledge production" (Willig, 2001, p.145) and regards data not as mirroring reality but producing knowledge that is useful to practitioners in explaining what they can see (Oliver, 2011).

2.3 Approvals

Approvals for the study were obtained from a Research Ethics Committee and the Research and Development departments of the host NHS Trusts (see Ethics Section).

2.4 Recruitment and consent

Service users at each site meeting the inclusion criteria were approached by a field contact and introduced to the study via discussion of a participant information sheet (PIS). A period of one week gave individuals opportunity to consider participation and discuss this with others if desired. After this time, they were revisited by the field contact and if interested in participating, consented via reply slip to meet the researcher to further explore the PIS and any questions. Interviews took place if informed consent was obtained, using a protocol to assess comprehension and voluntariness adapted from Thomas and Stenfert Kroese (2005). All potential participants were deemed able to provide consent and signed a consent form. Following interview, participants were provided with a debrief sheet.

The materials referred to are located within the Ethics Section. All were developed in line with Mencap easy-read guidance (2009), and accessibility reviewed by a self-advocacy group of PWID.

2.5 Interview procedure

Audio-recorded semi-structured interviews, lasting between 16 and 66 minutes, were conducted in private rooms in the secure units where participants resided. To minimise

acquiescent response patterns (Beail, 2002), guidelines for interviewing PWID were adhered to (Prosser & Bromley, 2012) and prompted emphasis of there being no correct answers and the use of closed or more factual questions in response to apparent uncertainty, with clarification-seeking then encouraged. The research supervisor reviewed audio-recordings of the first three interviews and made further quality-improvement suggestions. During the interview, participants selected a pseudonym, which was applied to their transcript to preserve anonymity, and at the end were debriefed and asked if they wished to receive an (accessible) copy of the findings.

2.6 Data collection and analysis

Within GT, data collection and analysis do not occur in linear sequence but take place simultaneously (Charmaz, 2014). Three interviews were initially undertaken, transcribed and subject to initial coding. This involved line-by-line analysis at a descriptive level, using participants' language and gerunds, to identify processes closely grounded in the data. Reoccurring initial codes were subsumed through focussed coding into tentative conceptual categories to explain larger segments of the data at a more abstract level (see Appendix A). This focussed coding process enabled the interview guide to be modified to explore emerging concepts and gaps in participants' accounts (see Appendix B).

A further cluster of three participants were interviewed, with the initial and focussed coding analysis repeated and interview guide adjusted if necessary, followed by the final cluster of interviews (see Figure A.1). During this iterative process, the constant comparison of data in and between transcripts highlighted similarities and differences in the emerging codes and conceptual categories. These were explored within subsequent interviews and, if appropriate, revised through analysis. Reflections and interpretations prompted during constant comparison and the creation of codes and categories were recorded in memos to further guide and enhance theory development. This process facilitated refinement of the

final conceptual categories, the conditions in which they operated and their processual links, from which the theoretical model of the process of DBT engagement and change, grounded in participants' data, was built.

Theoretical sampling of participants was planned to further "elaborate and refine…emerging theory" (Charmaz, 2014, p. 192); however, the small pool of potential participants meant all who consented were interviewed. Two follow-up interviews comprising confirmatory questions to test categories were instead conducted as a means of shaping the emerging theory. Additionally, the sample included individuals who had completed, dropped out, or were currently undertaking DBT, thereby providing negative case comparisons and increasing conceptual variation to enable a comprehensive theoretical understanding of the mechanisms affecting engagement.

[INSERT FIGURE A.1]

2.7 Quality and reflexivity

Charmaz (2014) argues for recognition by the researcher of their own values and interpretations as impacting the theory developed. Contemplations were recorded within memos of potential biases influenced by experience of delivering group psychotherapy in forensic settings, albeit with a non-ID population. To promote reflexivity and responsivity within the analytic process, these considerations along with all emerging codes and conceptual categories were critically reviewed with the research supervisor during regular supervision. These meetings facilitated reflection on previous interviews, emerging areas of interest and any personal assumptions, enabling revision and improving credibility of the GT.

3. Results

From the analysis, a model was developed of the process of service user engagement with DBT, how this relates to perceived change, and the elements that impede service users' understanding and use of DBT skills. The description of the model in this section should be read alongside its diagrammatic representation (see Figure A.2).

The core category of *uphill and downhill journey of skill use* explains how participants engaged with DBT and began to learn and apply its skills. It provides an explanatory and predictive account of all categories and their relationships within the model and, accordingly, of the core experience of participants undertaking DBT. The category comprises a number of subcategories conceptualised as stages, each of which must be passed through before an individual can move on to the next. This, however, was not a unidirectional process, rather a progressive and regressive journey that also highlights potential sticking points, thus explaining variation in participants' level of engagement and change. Key factors included participants' motivation, perceived threats to safety and belief in their ability to change, and their interactions with DBT facilitators and ward staff. These factors exerted influence at various points throughout the process, and are discussed accordingly and in relation to the categories in which they operated.

The core category is set within the wider context of three supporting categories: *extrinsic compliance*, *sense of safety*, and *belief in self*. These shall be discussed first to delineate this context and their function in relation to the *uphill and downhill journey of skill use*.

3.1 Extrinsic compliance

This initial category of the model focussed on individuals' motivation to commence DBT. Although DBT was not a mandatory treatment, engagement was viewed as a non-choice. Prior to undertaking the programme, participants described themselves as not

attempting to control the aggressive behaviour they directed towards themselves or others and as not seeking emotional support: “I didn’t have no skills to use” (Miss Ward #2). From introductory explanations provided by facilitators and care team staff, participants understood that by completing DBT they could stop behaving aggressively and be permitted transfer to a lower security unit. Despite seeing no intrinsic benefit to ceasing their aggression, all were aware that non-aggression was a prerequisite to progression towards release: “No, I didn’t need to change. Thought I had no choice though to get out” (Beyoncé). Participants considered themselves unable to make the required behavioural changes and thus compliance with DBT became regarded as the only viable means of achieving progression.

This extrinsically motivated compliance remained pertinent throughout participants’ engagement with DBT, maintaining perseverance, the attendance of individuals who considered quitting, and the continuation of skill use by those making progress towards release: “if I don’t use them I’ll get in trouble and be straight back in here” (Katie).

3.2 Sense of safety

This category referred to how individuals’ perceived vulnerability altered over the course of the programme. This was conceptualised as a cycle in which developing trust that others would not abuse their vulnerability was either promoted, thus initiating safety within group, or obstructed, leading to perceptions of being unsafe becoming heightened and eventually intolerable.

Upon commencing DBT, participants experienced anxiety being part of a group with their peers: “Nerve-wracking…didn’t know if I could trust them” (Alesha). This *lack of trust* stemmed from fear of negative judgement: “They might talk about me behind my back and with people not on the group and what they’d think of me” (Miss Ward #2). *Lack of trust* linked to initial difficulties comprehending the DBT material: “I couldn’t focus…more concerned about…watching my back” (Charlie).

To minimise the threat of vulnerability created by *lack of trust*, participants employed *silence*, contributing to discussions only when directed by facilitators and providing superficial answers. This maintained *lack of trust* by precluding counter-evidence and quickly presented its own risk to safety, with facilitators emphasising proactive contributions as necessary and asking individuals to discuss recent incidents. Participants endeavoured to alleviate the consequences of these prompts by sharing fictitious versions of events: "I'd blag the real reason I got angry if it was embarrassing" (Emmanuel). Despite all acknowledging using this strategy, none seemed aware that others might be doing the same and regarded what was shared when *someone speaks* as genuine and exposing.

Some observed *negative consequences* of contributions: "they'd laugh at what people said…putting yourself in a vulnerable situation they'd use to wind you up" (Iyaz #2). *Negative consequences* reinforced *lack of trust* and maintained participants' *silence*, thus preventing group safety being achieved. This cycle was broken by those members identified by facilitators as contravening the group confidentiality rules being deselected. However, this did not occur for one participant who subsequently never felt safe, leading to her decision to quit: "I just couldn't…put up with how much more stressful being in group was than doing nothing" (Charlie).

Most participants recognised *no negative consequences* of contributing, which began to shift perceptions of peer trustworthiness: "It grew as they didn't share things or laugh and they were saying things too they wouldn't want people to say…to others not on DBT" (Alesha). This set in motion a gradually developing *sense of safety*, initially fragile yet strengthened each time evidence of trustworthiness was provided by group members, and further influenced by events occurring within, and that shall be discussed under, the core category of *uphill and downhill journey of skill use*.

3.3 Belief in self

This category acknowledged individuals' core sense of lacking the capability to learn and utilise new information and skills, and details how this shifted during their engagement with DBT. However, rather than a linear improvement, these changes in perception undulated in parallel with events in the core category that challenged or reinforced individuals' initially low belief in their ability.

Upon commencing the group, all believed the DBT skills they were introduced to could overcome aggression as this is what they were told by staff; however, participants doubted their ability to effectively implement these skills and achieve such change: "I didn't think I'd be able to do it…It'd all go wrong" (Beyoncé). This pervasive low *belief in self* was underpinned by recollections of perceived failures, stemming from struggling to comprehend and retain learning at school, and accepted as an inherent deficit: "I just struggle" (Beyoncé); "you've got to make it easy for me to understand" (Pete). Some explicitly located these difficulties within an identity of themselves as intellectually disabled: "I think because we've got learning disabilities we find it hard to understand things as well as other people" (Emmanuel).

Individuals' ingrained low *belief in self* was exacerbated by the written and discussed DBT content, with this "too confusing, not explained clear enough" (Katie) and having "all these big names…abbreviation of loads of different things" (Emmanuel). Moreover, participants felt insufficient time was provided for them to understand skills, and struggled learning a new skill each session: "I can't keep it all in my head" (Ziziu).

3.4 Uphill and downhill journey of skill use

The journey through this core category involves participants' initial dilemma around using DBT skills, the strategy employed to appear compliant and avoid reprimand, the

subsequent rewards they obtained, followed by the pressures created by using DBT, the shift to an internalised belief in skills, and the destabilising effect of unfamiliar situations.

3.4.1 Having to do what I cannot

From the first group session, participants entered a vicious cycle of perceiving themselves as incapable yet having to use DBT skills. Consequently, they felt unable to undertake roleplays in session or complete their homework and manage their aggressive behaviour outside of group. Not wanting to highlight their incomprehension and therefore heighten their vulnerability, participants hid their confusion and remained unaware that others were also struggling, which perpetuated their low *belief in self*: "I'd be embarrassed explaining in front of everyone. I'd feel silly as the only one not getting it" (Alesha).

Participants quickly learnt that any display of aggression, non-completion of homework or refusal to roleplay would be scrutinised, with facilitators requesting explanation and using incidents to encourage skill use. This was experienced as punishing and demeaning: "I'd get told off for not doing it…Then they give me today's homework and I've got two to do" (Beyoncé); "…get moaned at by tutors, 'why didn't you do this?' or 'why didn't you ask for help?' and that's annoying, well embarrassing really" (Pete); "they keep saying go on, roleplay it! I feel even more stupid after" (Katie). Participants blamed themselves for these negative experiences, reflecting on how facilitators were "just trying to help and didn't know I was struggling because I didn't say" (Ziziu).

Fear of using skills was exacerbated by the requirement to begin demonstrating behavioural change: "they tell you…they'll know you're using skills because you won't behave as bad…You've got not be aggressive at all to make progress" (Iyaz #2). Prior to this, participants had not considered the active role they would need to take to cease their aggression, instead assuming this would be an automatic product of completing DBT: "I just needed to finish the group" (Miss Ward #2).

3.4.2 Isolation

To exit this highly pressured cycle of being expected to employ skills they did not understand, participants decided they had no choice but to take some action to manage their aggression: "I was even more worried about not moving on…so you pick the lesser of two evils" (Pete). However, they were unwilling to reveal their incomprehension by seeking help or incorrectly attempting skills for fear of jeopardising progression: "staff would see you weren't doing well at DBT and you'd look bad" (Katie). Instead, participants avoided becoming, or being observed as, aggressive by isolating themselves: "I'd self-harm if I went in my room so I sat on my own in the quiet lounge, so staff could see me doing something different, reminding myself of getting out by looking at family photos" (Alesha);

> I had paranoia of doing skills wrong…just did what I knew would give enough evidence, go to my room, stay there. I'd be angry and hit my pillow but no one knew so it looked good for me, I wouldn't be kicked off for not learning or lose my leave. (Iyaz, #2)

3.4.3 Positive reinforcement

Isolation came to be viewed positively due to the rewards it generated. Although participants whose aggression resulted from a more gradual culmination of negative emotions more consistently avoided incidents than those whose aggression was easily triggered and instantaneous, all improved in their behaviour and ward staff and DBT facilitators thus expressed approval: "by not getting dragged into arguments I would get praise from staff for keeping my head down" (Charlie). Participants were also able to complete homework entries which further elicited praise: "they said I did it right and I'd feel proud". Consistent reduced aggression led to participants being considered for or granted community access and home visits, bringing them closer to their extrinsic goals: "I was told if I wasn't getting into bother

I'd get my leave. And I did. I felt proud and it motivated me because I knew I'm moving on" (Iyaz, #2).

These benefits improved participants' *belief in self*: "It felt good, thought I wouldn't be able to do it but I'm actually learning and doing well using it for the first time ever" (Emmanuel). This was reflected on as "a new thing, feeling proud of my behaviour instead of ashamed" (Pete). Participants' understanding of what it meant to utilise DBT was shaped by these experiences, despite them engaging in isolation rather than DBT skill use which created new challenges. Their belief in the effectiveness of skills also shifted from credulous faith to personal confidence: "I understood why they said DBT was so good" (Katie).

3.4.4 The pressure cooker

This sub-category reflects how following rewards, participants experienced pressure to exert greater control over their behaviour, moving them back to the initial cycle of this core category.

Observing success in the reduction of aggression, ward staff increased their encouragement of participants to use DBT skills. This was experienced as a withdrawal of care, with independent self-management promoted 'too soon': "Rather than comforting or helping me like they did, they're constantly just saying 'use your DBT skills'…It's like they can't be bothered anymore" (Miss Ward #1). In parallel, facilitators also prompted participants to expand their repertoire by utilising more complex relational skills: "They said I had to start using the other skills to be more assertive" (Alesha). In contrast with perceptions of ward staff, this was perceived by participants as facilitators' expert investment in participants: "they know what they're doing because they've trained in DBT, not like nurses, and they're just trying to help us to get out in the community" (Katie).

The responses of facilitators and ward staff led participants to feel under increased pressure to consistently and effectively use DBT skills. With emphasis now on skills that

necessitated interaction with others, participants recognised they could no longer hide their difficulties using *isolation*. *Belief in self* again reduced and participants re-entered the initial cycle of *having to do what I cannot*, yet the rewards gained so far compelled them to maintain their progression towards release by attempting the complex DBT skills. They initially experienced failure which amplified the perceived pressure and reduced care from staff. With reliance on *isolation* having precluded acquisition of non-aggressive strategies to manage such stress, participants' likelihood of becoming aggressive increased.

This created a sticking point within the cycle for individuals whose aggression was easily and regularly triggered, and prompted them to abandon complex skill use and resume *isolation*:

> I'd get stressed, mind would go blank so I'd end up going to my room…then I'd be worrying or angry about doing it wrong and end up self-harming or kicking off so I'd lose my trips out anyway. Staff would ask why I didn't use my skills and inside I was like I tried but I couldn't! ...I just stopped trying them skills and stayed in my room (Charlie)

In contrast, those with a greater ability to resist engaging in aggressive behaviour had more easily eliminated their observed aggression and obtained greater rewards using *isolation*. Their progression towards release thus appeared more tangible, providing greater motivation to endure the pressures accompanying the use of new skills and resist the urge to alleviate stress through aggression. These participants experienced ward staff and facilitators as sympathetic to their difficulties with the complex skills and, recognising their efforts were appreciated, found a way out of *the pressure cooker* by drawing on staff support: "I didn't have a clue so couldn't use them right…that'd look like I wasn't trying…so I had to ask for help" (Pete).

Although pressure to use more complex skills exacerbated participants' difficulties, as these were no longer hidden by *isolation*, anxiety reduced: "I saw others struggling too so didn't feel as bad" (Beyoncé) and *sense of safety* increased: "we were all in it together" (Ziziu). This enabled those stuck in *the pressure cooker* and considering quitting to remain on the group.

3.4.5 Deconstructing "a better person"

This sub-category refers to how participants who started to seek support became able to comprehend and apply skills. This was largely achieved through the deconstruction of their difficulty with skills using diary cards and chain analyses within one-to-one sessions, which previously had been ineffective as participants were unwilling to acknowledge barriers. Through deconstruction, these participants gained insight into their struggles, providing motivation and dissipating *the pressure cooker*:

> I was still nervous using skills…But [facilitator] said it was better to try…I felt less worried doing it wrong and looking bad as staff knew I was trying, and I tried other skills because I thought they might work too now I was less worried. (Alesha)

Participants' skill use was refined through this coaching process and they reflected on managing situations that would previously have resulted in restraint, and recognising situations where if they had used a skill, the outcome would have been more positive. Although still motivated by their extrinsic goal of release, participants' *belief in self* also greatly improved, with all stating that DBT enabled them to become "a better person". Reliance on *isolation* reduced as they now felt equipped to manage interpersonal interactions, and homework and roleplays became a safe means of trying out skills. All described strong attachments towards facilitators, which reflected their experience of having someone consistently willing to listen to and not judge them as novel.

These participants' growing openness and confidence in self and skills transferred to group sessions: "I wanted everyone to learn and benefit as much as me" (Beyoncé). They offered advice to other group members on how to effectively use skills, which was empowering: "they allow us to be the therapists just as much as they are" (Emmanuel), and further increased participants' *belief in self*: "It felt good knowing I've helped someone and they've gone away and used it better" (Pete). This augmented the *sense of safety* within the group and motivated those who had not reached this stage to also seek help from facilitators, thus moving them from being stuck in *the pressure cooker* to the *deconstruction* stage.

3.4.6 Setbacks and motivation

This final sub-category accounts for why relapses in aggression or a decline in motivation can occur for individuals who appear to have made significant progress in DBT. Although participants fully embraced DBT due to its "life changing impact" (Katie), aggression still arose in some situations either unintentionally, due to high arousal following distressing news, or intentionally due to perceptions that it would be more effective in response to aggression from other service users. Despite awareness of the repercussions, participants identified benefits of aggression that DBT could not provide, including catharsis and "feeling powerful" (Iyaz #1). Other situations led participants to feel demotivated and wary: when skills did not work it was "disappointing and frustrating" (Pete) or they created unwanted consequences: "They said instead of them saying for me, I should raise it with my consultant as it'd be good practice…I refused and never told them anything important again as it was too scary" (Alesha).

If staff were viewed as responding to these setbacks with punishment they became a 'sticking point' for individuals and moved them back into *the pressure cooker*. At all stages, however, participants remained extrinsically motivated, acknowledging that without their goal of release, they would be unlikely to invest the effort required to employ DBT skills.

[INSERT FIGURE A.2]

4. Discussion

In line with the research aim, the model constructed within this study provides an understanding of the process of service user engagement with DBT and how this influences change. Fundamentally, DBT provides the motivation and means for individuals to address their intra or interpersonal aggression in order to progress towards release. Through enabling such behavioural (and a degree of cognitive) change, this temporal process is ultimately extrinsically—and, for those who reach the final stages, intrinsically—rewarding. However, the model also illuminates mechanisms that are of concern in respect of the difficulties individuals endure to achieve such change.

The model's opening category, *extrinsic compliance*, provides salient context to the overall process and difficulties therein. Consistent with previous accounts of PWID in secure services (Burns & Lampraki, 2016; Griffith, Hutchinson, & Hastings, 2013), participants regarded their aggression as functional, and subsequently were not intrinsically motivated to desist. The perceived forced-choice of undertaking DBT to achieve release reflects the culture of compliance within forensic services, where non-compliance with authority and treatment targets is considered indicative of risk of recidivism and prohibits release (Weaver, 2014). Indeed, McCann, Ball and Ivanoff (2000) acknowledged forensic service users' dialectical dilemma of "freedom to participate in treatment versus the experience of treatment as coercion" (p.455).

Within this context, participants' difficulties within the model resonate with Atherton's (1999) theory of "supplantive learning" (SL): acquiring new skills to replace previous ways of acting. SL incurs psychological cost by diminishing self-esteem and prior

competence (here, coping through aggression), which further reduces skill "feasibility" (Gollwitzer, 1990). This perception informs self-efficacy and is based on past experiences, which for participants constituted failures. When SL is coercive, it leads to avoidance of situations that may reveal incompetence and incur judgement, as with participants' *isolation* (Blackwell, Trzniewski, & Dweck, 2007). Although SL relates to the categories of *belief in self, having to do what I cannot* and *the pressure cooker*, as a theory of individual learning it does not account for group *sense of safety*. Furthermore, its suggestion that learning is embraced following introduction of a facilitative environment (Atherton, 2013) echoes *deconstructing "a better person"*, yet does not explain how this occurs.

Comparison of the model with self-determination theory (SDT; Deci & Ryan, 2008) offers more coherent similarities. In contrast with other theories of motivation and change, such as the transtheoretical model (Prochaska & DiClemente, 1986), SDT alone considers the influence of internal versus external motivation. Parallel to *extrinsic compliance*, SDT suggests individuals lack motivation for therapy when perceiving no benefits of change or their incompetence as rendering skills ineffective, yet engage due to coercive reward, such as release from services (Ryan, Lynch, Vansteenkiste, & Deci, 2011). Aligned with *having to do what I cannot*, *isolation* and *the pressure cooker*, SDT posits that feeling obliged to successfully execute skills is strongly associated with fear of negative evaluation and failure, leading to thoughts and emotions being hidden (Sideridis, 2006) and barriers to change experienced as more formidable.

Within SDT, individuals become active and willing, rather than coerced, therapy members who internalise behavioural change when supported to gain basic psychological needs for autonomy, relatedness and competence; the latter two reflecting the model categories of *sense of safety* and *deconstructing "a better person"*. Autonomy develops from individuals using their personal values to guide choices without pressure, therefore, praise is

experienced as undermining when used to motivate specific behaviour, as by ward staff within *the pressure cooker*. It could be argued that participants never fully gained autonomy as, indicative of their forensic setting, compliance with behavioural expectations is required. Thus, SDT departs from the model in suggesting that autonomy is required for competence to develop, whereas for participants the successful application of coerced skills enabled intrinsic motivation to develop. Nonetheless, SDT again converges in arguing that insofar as rewards/punishments are exerted and change externally motivated, behaviours are unlikely to be maintained once contingencies are removed (Lamberti et al., 2014), as highlighted by participants within *setbacks and motivation*.

One recurrent element within SL, SDT and the current model is the destabilising impact of new learning on *belief in self*. This echoes the skill struggles and considerations of dropout reported by ID DBT participants in this and other studies (Baillie & Slater, 2014; Johnson & Thomson, 2016; Morrisey & Ingamells, 2011; Sakdalan et al., 2010). Whereas PWID often tend to reject their ID label (Dorozenko, Roberts, & Bishop, 2015), some participants attributed these difficulties to having an ID. This may reflect internalisation of the DBT principle of self-acceptance or, with identities of PWID complex constructions based on their social roles (Dorozenko et al., 2015), reflect a less stigmatising and more tolerable account of their aggression and detention than an offender identity. Moreover, it is likely difficult to reject an ID identity when detained in an ID-specific unit and receiving ID-adapted therapy that you are struggling to learn and apply.

Participants' reluctance to use skills necessitating interpersonal interaction resonates with negative social situations being the greatest source of stress for PWID in both community and forensic settings, who subsequently employ avoidant isolation as a coping strategy (Hartley & MacLean, 2008; Burns & Lampraki, 2016). Although *isolation* could be presumed to impact on participants' psychological wellbeing (Kuster et al., 2015), the

positive reinforcement it elicited moderated adverse effects and rewarded its continuation. This echoes the findings of Hartley and MacLean who suggested isolation may benefit PWID who typically have limited interpersonal control over their environment, particularly in forensic settings. However, they further cautioned against prolonged isolation, highlighting the potential for disempowerment and distress. Participants perhaps avoided such outcomes as they were unable to rely indefinitely on *isolation*, being moved into *the pressure cooker* where they did experience distress and again coercion.

The anxiety created within *the pressure cooker* and *setbacks and motivation* by facilitators' "consultation-to-the-patient" strategies, which involve participants attempting tasks staff would usually undertake, are acknowledged as an initial yet rewarding "shock" (Linehan, 2015, p.98). However, consultation-to-the-patient appeared destabilising and threatening for participants, who may have had little prior opportunity to exert self-determination (Kelly, 2016). *The pressure cooker's* subsequent exacerbation of the urge to aggress towards others or self may elucidate the trend of an initial spike in risk-related behaviours observed in DBT groups for PFID (Brown et al., 2013; Lew et al., 2006; Sakdalan & Collier, 2012).

No participant described increased risk post-DBT; therefore, iatrogenic harm may not have been sustained (Parry, Crawford, & Duggan, 2016). This could reflect the increased *sense of safety* prompted by *the pressure cooker*: with *isolation* no longer viable, participants' struggles with skills were now observable or exposed through them seeking help, thus providing powerful awareness of others as also struggling and generating a sense of belonging. This "universality" is regarded a key therapeutic factor for enabling engagement and change (Yalom & Leszcz, 2005) and indeed created a secure base for participants' exploration of experiences, understanding and skills within *deconstructing "a better person"*. Such opportunity for self-reflection is described as particularly powerful for PWID, who

previously may not have been encouraged to (re)interpret their behaviour (Verhoeven, 2010) without pejorative judgement and penalties. Furthermore, recognition of enduring the demands of DBT while improving self-regulation is likely to have further revised participants' mental representations and augmented *belief in self* (Rizvi & Linehan, 2005).

The cycle through which participants developed a *sense of safety* has similarities with Yalom and Leszcz's (2005) group cohesion loop: trust–self-disclosure–empathy–acceptance–trust. This sequence largely mirrors the findings; however, participants' initial self-disclosures were precipitated by—and negatively reinforced through removing—facilitator pressure, with trust absent prior to sharing. This starting point may, therefore, more realistically account for how trust originates in Yalom and Leszcz's loop than their suggestion of courage. Moreover, this resonates with the proclivity for distrust and insecure attachment styles of PWID (Fletcher, Flood, & Hare, 2016), particularly in forensic services (Taylor & Novaco, 2013), and clarifies the analogous finding by Johnson and Thomson (2016) of initial peer mistrust within a secure ID service DBT group.

4.1 Limitations

Potential researcher bias was minimised and credibility of findings improved through quality checks of the data collection and analysis performed by a researcher experienced in GT, along with utilisation of a reflective diary and memoing to discern assumptions. Seeking participant feedback on the findings would have furthered co-creation of meaning and validation of the model; however, this was not feasible within the timeframe available.

A further potential limitation relates to participants having to retrospectively recall their experiences of DBT, with some having started the group one year prior to their involvement in the study. Thus, their recollection of events and affective states may have differed from their perspectives at the time, and been influenced by current contextual factors (e.g., progress towards release, life stressors) and potential difficulties with retrospective

memory highlighted in PWID (Levén, Lyxell, Andersson, Danielsson, & Rönnberg, 2008). Longitudinal data collection, conducted at various points throughout the process of DBT, may enhance current findings.

Data collection ultimately ceased due to reaching the limits of the available timeframe. It has been stated that interviews should continue until theoretical saturation is reached (Glaser, 1978). Others argue this is not congruent with constructivist GT, where the aim is not to provide an objective truth but sufficient theoretical insights into the process under study (Charmaz, 2014; Dey, 1999). The categories developed were present within all the interviews and final interviews data did not revise existing categories. Therefore, it would appear theoretical sufficiency was achieved.

4.2 Clinical implications

The model highlights the process of engaging with and change through DBT as largely motivated by coercion. It is perhaps antithetical to avoid focus on aggression reduction within forensic services; however, promotion of benefits other than release would likely reduce fear of failure and its perceived consequences. Moreover, developing general life-skills rather than aggression reduction is the immediate aim of DBT, with a focus on self-aggression found to increase such behaviour (Springer, Lohr, Buchtel, & Silk, 1996). Introduction of pre-treatment sessions utilising motivational interviewing techniques (Miller & Rollnick, 2002) could facilitate development of intrinsic motivation and thus increase persistence, positive affect and self-efficacy (Ntoumanis et al., 2014) and maintain improvements post-DBT (Urbanoski, 2010).

In respect of the pervasive fear of negative appraisal apparent within *having to do what I cannot,* Verhoeven (2010) acknowledges “not all individuals are willing or able to participate in a group as low self-esteem makes them reluctant to expose their cognitive challenges” (p.330). However, as detailed within the introduction to this paper, the emphasis

is usually on functional adaptations to overcome these challenges rather than bolstering self-esteem or self-efficacy. The lack of attention to these psychological barriers precludes full recognition of individuals' difficulties, the adaptations actually required, and their zone of proximal development (Vygotsky, 1962), hence prohibiting collaborative "consultation-to-the-patient" and awareness of any increased risk of harm. Thus, the potential for and consequences of participant difficulties—both functional and psychological—should be emphasised by DBT trainers, become an imperative discussion within group and in facilitators' team consultation, and be made explicit to potential participants to promote informed consent.

4.3 Future research

The model highlights the need for exploration of possible coercion and increased desire to aggress towards others and/or self within DBT for PWID. Debaters of therapy in forensic settings acknowledge its coercive nature; however, proponents contend that it ultimately supports autonomy by providing skills required for an independent and meaningful life, whereas others suggest it departs so radically from traditional therapy so as to constitute punishment (Lamberti et al., 2014). Elements of both arguments are evident within the model; however, the findings introduce the question of whether it is the pressure to comply with DBT or actually DBT itself that produces change. What is regarded by many as the "gold standard" of therapy evaluation, randomised control trials, employ control group comparisons, yet those not undergoing treatment are not subject to the pressures highlighted within the model, thus this approach may limit conclusions of effectiveness. Future research to monitor and address this issue and enhance treatment evaluation should consider mixed-methods, with phenomenological exploration of perceptions of whether coercion is a necessary part of the therapeutic process beneficial in advancing the understanding offered by the model.

A number of difficulties highlighted within the model, including extrinsic motivation, anxiety, incomprehension, and reduced self-efficacy, are acknowledged as aversive within DBT's training manual (Linehan, 2015). However, the strategies the manual proffers for overcoming these barriers were predominantly experienced as punishment by participants in the present study and elevated risk. This dissonance could reflect the manual not having been developed for PWID, or may indicate the extent and impact of aversion has been undervalued. Qualitative exploration of risk in mainstream and ID DBT would enable the current findings to be clarified and appropriately addressed, while adverse effects could be monitored using the Negative Effects Questionnaire (Rozenthal, Kottorp, Boettcher, Andersson, & Carlbring, 2016). Finally, the impact of pre-DBT motivational sessions could be evaluated through control group research.

4.4 Conclusion

The GT presents the first theoretical understanding of the process of engagement with DBT and related change for PFID. It does not constitute an absolute representation yet, in providing a substantive conceptualisation rather than description of the common process of engagement and change, may incorporate differing experiences (Glaser, 2004). The GT has identified key implications for DBT delivery, notably related to addressing group members' motivation for commencing the programme and explicit consideration of aversion, to safeguard increased harm. Awareness of the trajectory from compliance and avoidance to acceptance and generalisation enables DBT providers to align themselves with the individual, providing support as appropriate.

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Tables and Figures

Table A.1. Inclusion and exclusion criteria

Inclusion	Exclusion
English speaking Service users who have attended and completed an ID adapted DBT skills group Service users who began attending an ID adapted DBT skills group but 'dropped out' after three sessions Service users who are currently attending an ID adapted DBT skills group and have attended a minimum of three sessions	Service users who are deemed unable to participate in interviews by their Multi-Disciplinary Team (MDT) members Service users who are deemed unable to provide consent to interview following an assessment of their capacity to do so by the researcher

Table A.2. Participant demographic information

Demographic	Information*
Age	Range 21-48 (*M*=30.3, *SD*=9.03)
Gender	4 males (45%) 5 females (55%)
Ethnicity	2 Asian British (22%) 7 White British (78%)
FSIQ	Range 59-72 (*M*=66.7, *SD*=4.03)
Location	5 located in a Low Secure Unit (55%) 4 located in a Medium Secure Unit (45%)

***** Participant demographic information has been provided for the sample rather than individual participants as a safeguard to protect anonymity

Figure A.1. Process of grounded theory analysis

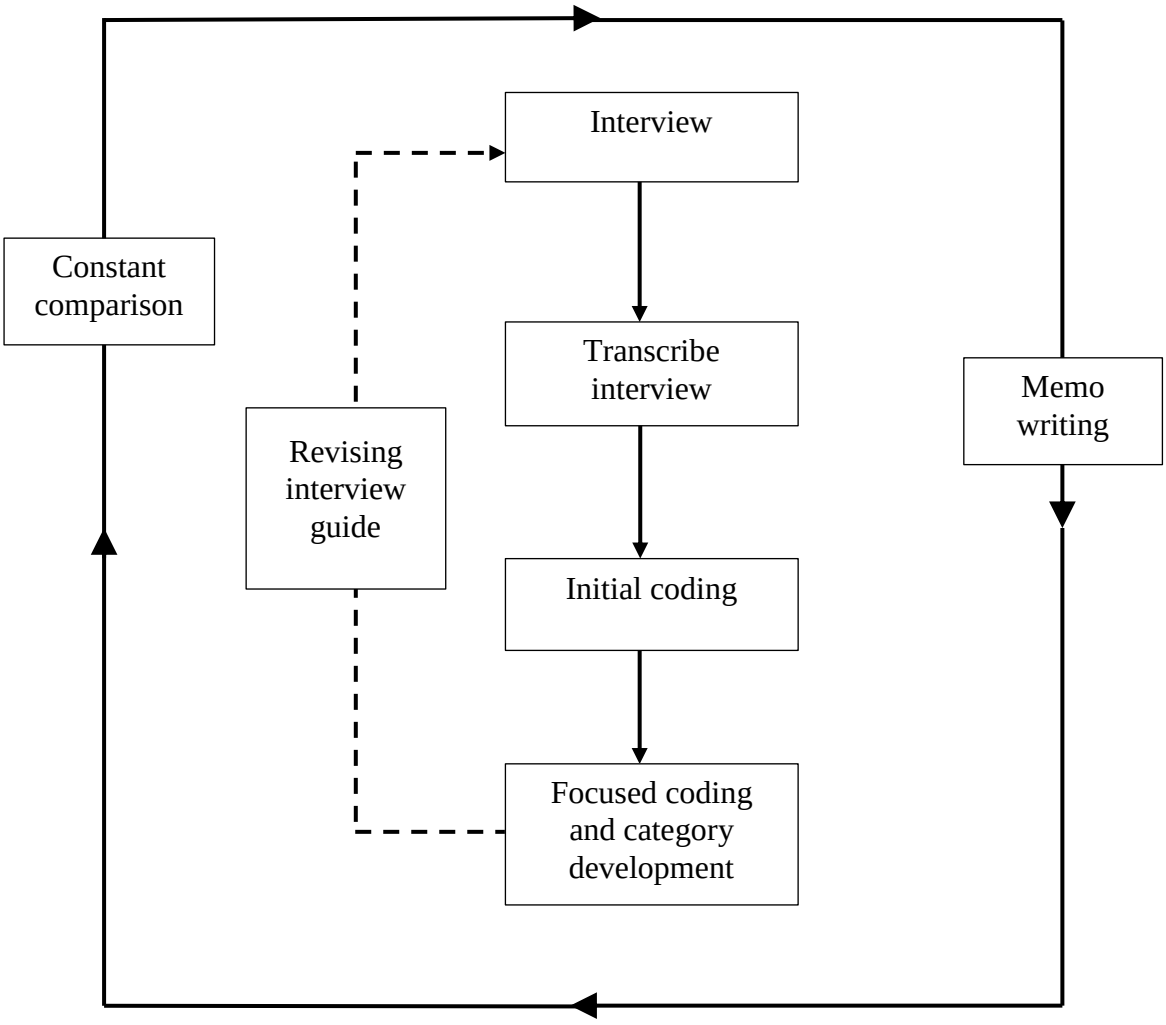
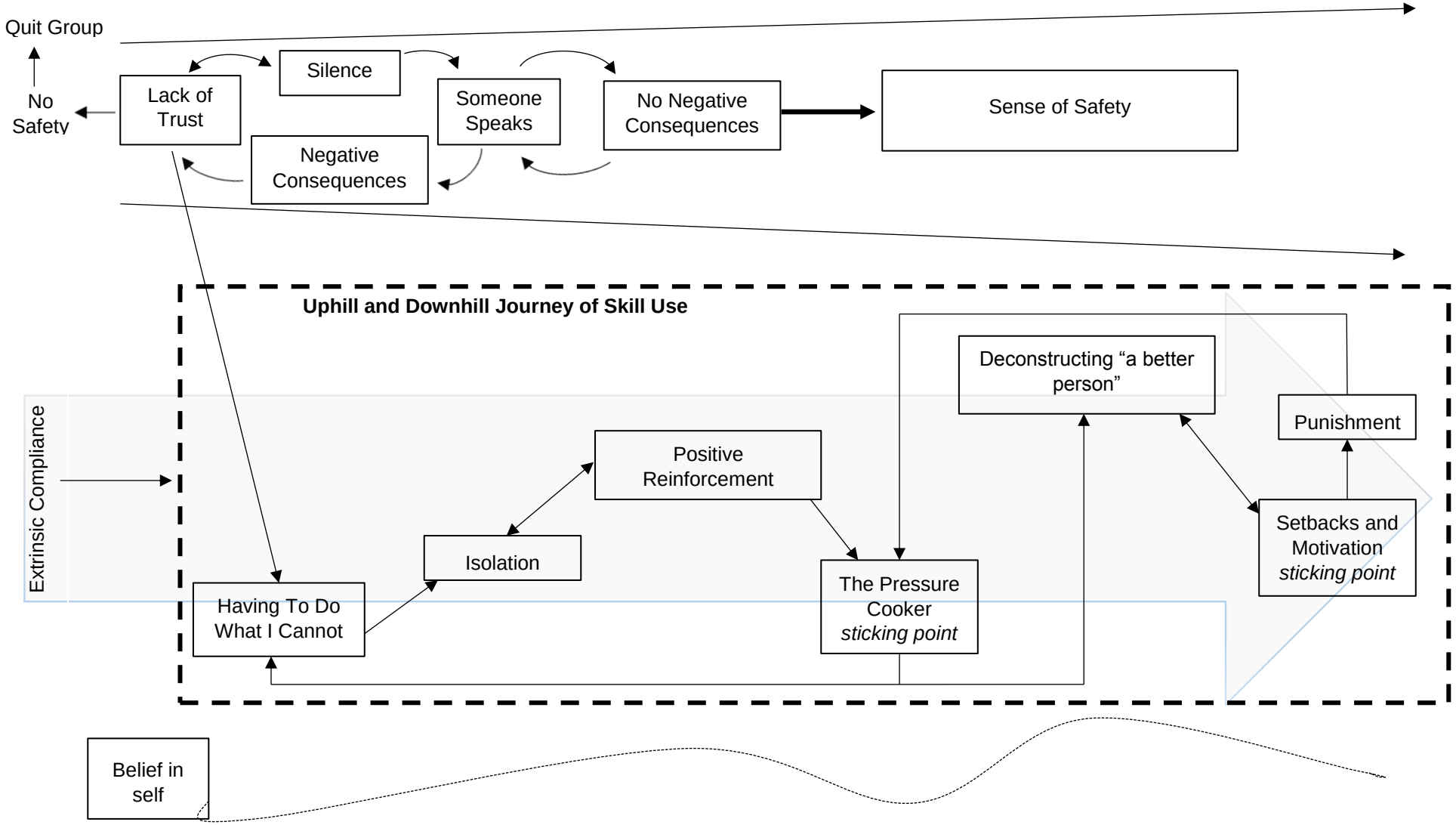


Figure A.2. Model of the process of engagement and change

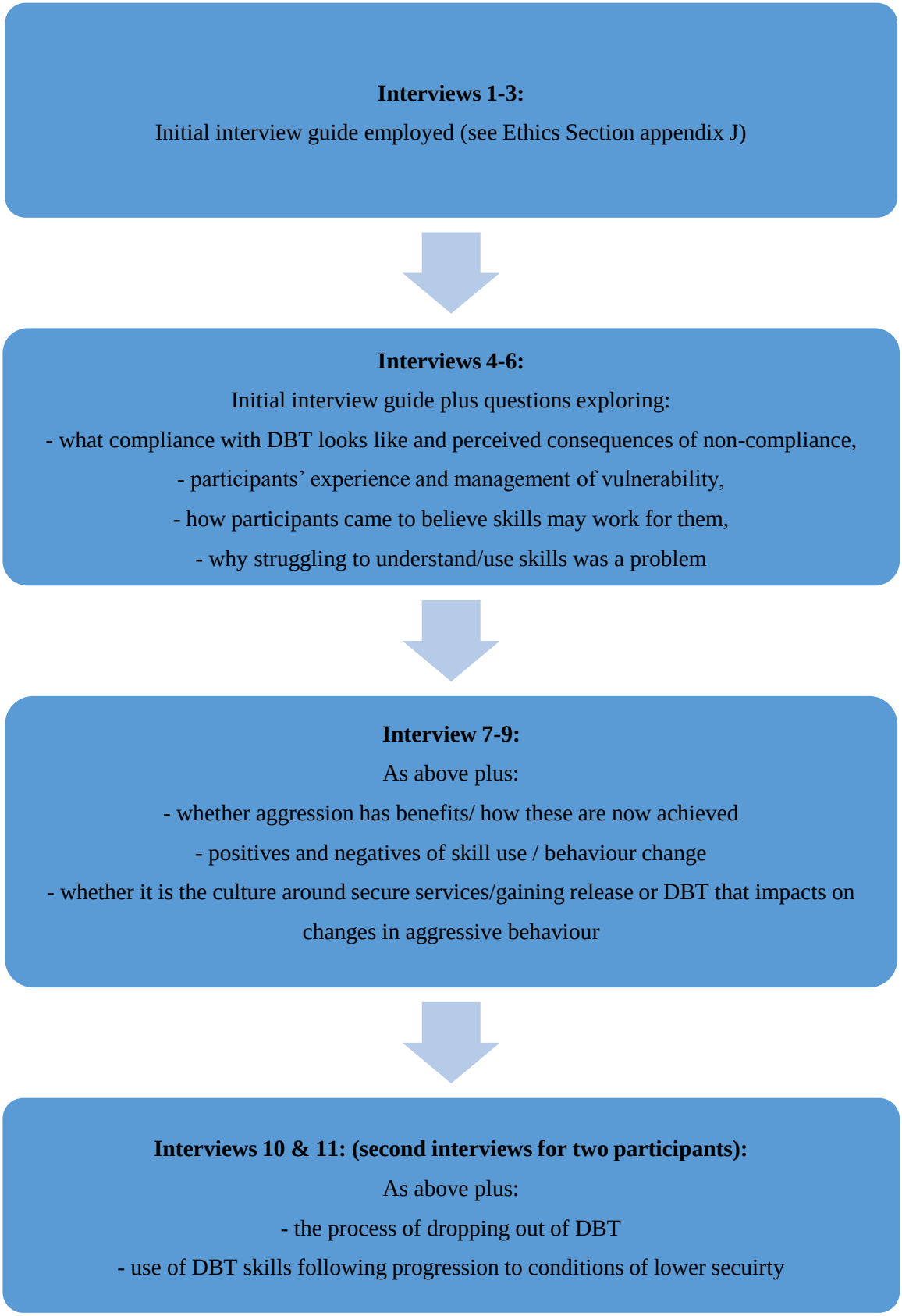


Appendices

Appendix A: Transcript excerpt with coding

Interview data	Initial code	Focussed code	Category code
Interviewer: So you said it was hard using the skills at first? **Iyaz:** It was yeah. I did though because I had that goal. But it was hard and I had the paranoia of doing it wrong and I didn't really understand what to do, understand why, and as well not feeling happy with the other people in my group because of those two idiots and I didn't know the others very well and I didn't want to get made fun of, so at first I just did what I knew would give the evidence, go to my room, stay there, I would be angry and hit my pillow but no would know so it looked good for me and then wouldn't be kicked off for not learning so it was hard but I knew I had to do it to get my goal, do you understand?	• Initially hard to use skills but did as believed had to in order to achieve goal. • Worrying about using skills incorrectly. • Didn't understand why should and how to use skills. • Unhappy in group due to disruptive others. • Uncomfortable as didn't know rest of group and didn't want to be made fun of. • Reducing observable aggression and vulnerability by using pseudo-skill of staying in room. • Still aggressive but no one could see. • Not displaying aggression looked positive. • Strategy allowed to remain on group by allowing to present as applying learning. • Enduring to achieve goal.	• Motivated to persevere with skills for goal. • Fearing judgement. • Barriers to skills. • Feeling vulnerable. • Use of pseudo-skill to evidence learning. • Having to reduce observable aggression to remain on group and achieve goal. • Complying with DBT to make progress/ move on – external motivator.	*Extrinsic compliance* *Having to do what I cannot* *Sense of safety* *Isolation* *Extrinsic compliance*

Appendix B: Overview of interview guide modification



Appendix C: Journal instructions for authors

BEHAVIOUR RESEARCH AND THERAPY

AUTHOR INFORMATION PACK

PREPARATION

Article structure

Subdivision - unnumbered sections

Divide your article into clearly defined sections. Each subsection is given a brief heading. Each heading should appear on its own separate line. Subsections should be used as much as possible when crossreferencing text: refer to the subsection by heading as opposed to simply 'the text'.

Appendices

If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

Essential title page information

• ***Title.*** Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.

• ***Author names and affiliations.*** Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lowercase superscript letter immediately after the author's name and in front of the appropriate address.

Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.

• ***Corresponding author.*** Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. **Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.**

• ***Present/permanent address.*** If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

Abstract

A concise and factual abstract is required with a maximum length of 200 words. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if essential, then cite the author(s) and year(s). Also, non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself.

Graphical abstract

Although a graphical abstract is optional, its use is encouraged as it draws more attention to the online article. The graphical abstract should summarize the contents of the article in a concise, pictorial form designed to capture the attention of a wide readership. Graphical abstracts should be submitted as a separate file in the online

submission system. Image size: Please provide an image with a minimum of 531 × 1328 pixels (h × w) or proportionally more. The image should be readable at a size of 5 × 13 cm using a regular screen resolution of 96 dpi. Preferred file types: TIFF, EPS, PDF or MS Office files. You can view Example Graphical Abstracts on our information site.
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Highlights are mandatory for this journal. They consist of a short collection of bullet points that convey the core findings of the article and should be submitted in a separate editable file in the online submission system. Please use 'Highlights' in the file name and include 3 to 5 bullet points (maximum 85 characters, including spaces, per bullet point). You can view example Highlights on our information site.

Keywords
Immediately after the abstract, provide a maximum of 6 keywords, to be chosen from the APA list of index descriptors. These keywords will be used for indexing purposes.

Abbreviations
Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in the footnote. Ensure consistency of abbreviations throughout the article.

Acknowledgements
Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

Formatting of funding sources
List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding has been provided for the research, please include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Shorter communications
This option is designed to allow publication of research reports that are not suitable for publication as regular articles. Shorter Communications are appropriate for articles with a specialized focus or of particular didactic value. Manuscripts should be between 3000-5000 words, and must not exceed the upper word limit. This limit includes the abstract, text, and references, but not the title page, tables and figures.

Artwork

Electronic artwork

General points

- Make sure you use uniform lettering and sizing of your original artwork.
- Embed the used fonts if the application provides that option.
- Aim to use the following fonts in your illustrations: Arial, Courier, Times New Roman, Symbol, or use fonts that look similar.
- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
- Provide captions to illustrations separately.
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- Submit each illustration as a separate file.

A detailed guide on electronic artwork is available.

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Please submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules.

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Web references

As a minimum, the full URL should be given and the date when the reference was last accessed. Any further information, if known (DOI, author names, dates, reference to a source publication, etc.), should also be given. Web references can be listed separately (e.g., after the reference list) under a different heading if desired, or can be included in the reference list.

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List: references should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters 'a', 'b', 'c', etc., placed after the year of publication.

Examples:

Reference to a journal publication:

Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2010). The art of writing a scientific article. *Journal of Scientific Communications, 163*, 51–59.

Reference to a book:

Strunk, W., Jr., & White, E. B. (2000). *The elements of style.* (4th ed.). New York: Longman, (Chapter 4).

Reference to a chapter in an edited book:

Mettam, G. R., & Adams, L. B. (2009). How to prepare an electronic version of your article. In B. S. Jones, & R. Z. Smith (Eds.), *Introduction to the electronic age* (pp. 281–304). New York: E-Publishing Inc.
Reference to a website:
Cancer Research UK. Cancer statistics reports for the UK. (2003). http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/ Accessed 13.03.03.

Chapter 3 : Critical Appraisal

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1. Introduction

The overarching aim of my thesis was to add to the current evidence base for psychological interventions delivered to people in forensic intellectual disability services (PFID). Prior to embarking on what has been, to borrow from my research paper, an *uphill and downhill journey of skill use*, I felt a great responsibility to choose my thesis topic carefully: The privilege of doctoral training has never diminished and I wished to use my research to "give something back". I was simultaneously overwhelmed at the plethora of potential topics but in needing to reach a decision, turned to the fields that, both before and during training, have evoked passion: working with people with ID and/or with forensic needs. Finally, awareness of the growing popularity of dialectical behaviour therapy (DBT) in secure services cemented the topic as one that could advance theory and thus be of utility for services and their users, but also provide me with a unique insight into the perspectives of PFID on "what works".

1.1 Thesis overview

The first of my thesis papers was a systematic literature review of the effectiveness of interventions targeting anger and/or aggression for PFID. The review tentatively offers support for the effectiveness of CBT in improving anger regulation, and of a range of modalities, including CBT, DBT, mindfulness and behavioural approaches, in reducing aggressive behaviour. Differing durations, intensities or formats of delivery had no appreciable influence on outcome. Finally, a sole CBT study offered support for the oft-assumed role of treatment-related anger improvement in reducing aggression in PFID. Nonetheless, the findings of the review were inconclusive due to the methodological shortcomings of the literature, which precluded conclusions on the longevity and generalisability of treatment gains. Despite the limitations of the studies reviewed, and of the review itself, by illuminating the current equivocal evidence and offering recommendations

for more robust approaches to future research and practice, I consider the findings of value to researchers and clinicians alike.

The second paper was an empirical study that recruited nine participants and utilised a grounded theory (GT)-informed methodology (Charmaz, 2014) to provide the first theoretical understanding of the process of engagement with DBT and related change for PFID. The GT highlights the core category of *uphill and downhill journey of skill use* as a "central corridor" through which DBT group members proceed in a non-linear fashion. This process occurs within the context of additional factors of participants' motivation for change, self-efficacy, and safety within the group, which exert influence on, and are influenced by, this journey. While participants gained extrinsic benefits in the form of progression towards release, their involvement with DBT was characterised by a sense of coercion and times of great struggle, which acted to increase the very behaviours—aggression towards self and/or others—that their participation in DBT aimed to address. These findings highlight important areas of future study, as well as vital implications for programme facilitators and direct-care staff supporting PFID attending DBT.

In this third paper I shall reflect on the strengths and limitations of my thesis, specifically focussing on challenges relating to conducting research with PFID and the prevalent theme, both within my research and more generally for this population, of coercion.

1.2 Barriers to conducting ID research

From the lectures I attended within the ID teaching during clinical training, I repeatedly noted the same message: The field of ID is under-researched. I subsequently was keen to contribute towards reducing the disparity between the mainstream and ID evidence bases and, in doing so, listen to and provide a platform for the voices within this marginalised population (Lumsden, 2013). With my empirical paper focussing on DBT, I had wanted to explore emotion regulation in people with ID. However, despite the call at the British

Psychological Society annual conference in 2001 for more attention to be paid within research to the "emotional lives" of people with ID (Arthur, 2003, p.25), few qualitative (and quantitative) studies exist (McClure, Halpern, Wolper, Donahue, 2009). Searching more widely for a novel meta-synthesis topic with some relevance to my empirical paper, I observed directly the issue commented on by my lecturers around the limited number of qualitative studies involving people with ID. Indeed, while Beail and Williams (2014) noted the apparent reluctance of mainstream journals to engage with ID research, they also highlighted that within three of the leading ID journals, qualitative studies represented the minority of publications. Furthermore, over half of the papers employing qualitative methods had family members and carers as participants, rather than people with ID.

I regard my empirical paper as usefully addressing the deficits I encountered within the literature, firstly through its use of constructivist GT, with its central tenet to give voice to participants (Charmaz, 2014). Second, my paper highlighted the extrinsically-driven motivation of PFID to change how they regulate their emotions, how expressions of emotion regarded by society as "problematic" provided benefits for my participants that the more prosocial strategies could not achieve, and how the difficulties encountered during DBT exacerbated emotion regulation difficulties. Furthermore, and unintentionally, my empirical paper contributes to the recommendation made within my systematic review: for future research to qualitatively explore the mechanisms for change and therapeutic processes experienced as useful by attendees of anger and/or aggression interventions. Turning to my systematic review, while its focus was on more specific aspects of emotion regulation than originally intended, anger and aggression are the most commonly reported emotional difficulties of people with ID (Emerson & Einfield, 2011), and subsequently those that this population are most frequently referred to for treatment. Despite the systematic review not creating a platform for the voices of PFID, in highlighting how the quality of anger and

aggression interventions—and thus the evidence base—should be advanced, it does contribute towards improving their experiences and the effectiveness of treatment they receive (National Institute for Health and Clinical Excellence, 2011).

Although not specifically seeking papers on PFID for my literature review, I noticed the even greater scarcity of studies conducted with this arguably further marginalised ID sub-group. This is despite formal recognition of the benefits of research with PFID by the UK government white paper Valuing People Now (Department of Health, 2009). While it perhaps should be expected that studies of a sub-group would be fewer than that of its overarching population, I also considered a number of additional hypotheses, the first of which related to detention in forensic services. Given the substantial societal and monetary costs of reoffending (Delves & Norfolk-Whittaker, 2013), the majority of research pertaining to individuals with forensic needs focusses on quantitative evaluations of interventions for reducing recidivism (Ministry of Justice, 2013). I wondered whether the lack of exploratory studies reflected the dissonance for some researchers, or their funders and wider society, between the empowering nature of qualitative research for service users (Given, 2008) and the status of those individuals in forensic settings, as having likely caused harm to others.

I acknowledge as conjecture the existence of a view that PFID do not "deserve" to have their voices in research. Such a view is *perhaps* worth consideration given that more generally, there appears to be some disregard for the opinions of forensic service users: Prison staff have been found to believe "prisoners did not deserve to have a voice" (Schmidt, 2013, p.16), government policies empower and prioritise victims over offenders in the development of forensic services (Armstrong & Weaver, 2013), and several countries do not allow prisoners to vote, despite the European Court of Human Rights deeming this a violation of rights (McKinney, 2016). Indeed, the lack of qualitative studies conducted with PFID has similarly been suggested to imply that research that listens to the voices of this population is

regarded as having limited value (Breckon, 2011). Whatever the reason underpinning this scarcity, my personal view is that denying individuals with forensic needs a voice is not only unethical but counter-productive. As demonstrated by my empirical paper, exploring the experiences of individuals is crucial for understanding how and why rehabilitative programmes are (in)effective, and thus generating a robust evidence base.

However, a further potential explanation for the paucity of research with this population did resonate with me, related to gaining research approval. This stemmed from my past difficulties with satisfying concerns for my safety highlighted by a Research Ethics Committee (REC) for a study involving prisoners, despite my working in the prison and having daily prisoner contact. I was also aware of a former trainee who faced barriers, including attendance at a REC specialising in participants "lacking capacity", due to the study's sample having mild ID (Breckon, 2011). My apprehensions were ultimately advantageous; prompting me to pre-empt potential REC concerns, including safeguarding risk and capacity by developing assessment and contingency protocols, and adding face validity to materials through consultation on their accessibility with experts-by-experience.

I subsequently experienced no difficulties in gaining REC approval; however, I had anticipated the process to be arduous and, if not highly motivated to undertake research with PFID, I may have been discouraged. Indeed, Gilbert (2004) highlights the patience and persistence required to conduct ID research, while within my training cohort, I was the only person to complete my thesis with ID participants and within forensic settings. This perhaps calls to question how ethical the ethics approval reviews are if, by (overly?) protecting vulnerable individuals, they are exacerbating the under-representation of PFID in research.

1.2.1 Recruitment

Further echoing Gilbert's (2004) forewarning of patience and persistence were the challenges I encountered during recruitment of both research sites and participants. My first

confirmed site suggested approaching the service that became my second site, as they had collaborated on research in the past. These two readily-engaged services had a smaller combined sample pool (14) than the total number of participants I hoped to recruit (15). Many more individuals had completed DBT at these sites but progressed to community services; on reflection, this mirrors the extrinsic rewards of DBT described by my participants. Also aware that not all potential participants may wish to take part in my study, I began searching for additional sites. Aside from my confirmed research sites, I had no contacts in forensic ID settings, and with services typically not advertising the therapies they deliver, I had to identify prospective forensic ID DBT sites by looking at where authors of relevant publications and presentations worked, seeking suggestions from professionals I met at training events, and exploring the private and charitable sectors.

Eight of the nine services I identified were very positive about the value of my study but declined involvement, stating they did not have the time to assist. Research can be regarded a luxury requiring time; however, without contributing to the evidence base, we run the risk of delivering ineffective interventions that in the long-term serve to increase service demands (Breen, 2014). I was subsequently grateful when the ninth service I contacted appeared keen to act as my third research site. However, I experienced difficulties in maintaining consistent communication, and eventually had to accept that recruitment of participants from this site was unlikely to occur within the timescale of my study; unfortunately I was also left with insufficient time to seek a replacement site. I consider these difficulties as highlighting another challenging factor in conducting research with PFID. Such individuals are located within specialist, and consequently geographically spread, services, which by their very nature as secure units, are difficult to access. This made it difficult to develop a connection with this site, whom I had reached out to and had no prior relationship with as I did with my first site, who provided a mutual connection to my second

site. I regard this as preventing the site from investing in me and my research, and within the likely context of competing demands highlighted by the services that declined involvement, this site had little incentive to prioritise my project.

In contrast, recruitment at the remaining two sites started positively. By October 2015, I had interviewed three participants at my first site, while simultaneously my second site confirmed expressions of interest. Hereafter, unforeseen difficulties arose at both sites that hampered communication and delayed recruitment and data collection further. I recognised from this that even for staff who are genuinely invested, in the context of competing work demands, research can become a lesser priority. For future research, I would endeavour to develop with sites from the outset a clear timetable for recruitment and interviews, and ensure all communication is consistently circulated between a team of contacts to avoid one person becoming responsible for all research-related tasks.

Furthermore, while I have predominantly worked in (non-ID) forensic settings and considered myself attuned and responsive to the associated power imbalances, these frustrating delays afforded valuable experiential insight into the control staff have over the lives of service users. My potential participants generally did not leave the units in which they were detained, making them potentially more available than community participants (Bampton & Cowton, 2002). Yet whether and when, and sometimes for how long, I met participants—despite their interest in the study—was entirely dictated by staff. While not condoning the behaviours displayed by people with ID that challenge services, I could empathise with service users' frustrations and desire to gain control within these highly controlling environments (Emerson & Einfield, 2011).

1.3 Coercion in research with PFID

Related to power, a key concern I anticipated but did not encounter during ethics approval was participant coercion. To reduce perceived researcher pressure and subsequent

acquiescence, my recruitment procedure set out that I would access potential participants via staff. The staged consent process was also implemented to reduce perceived coercion, as well as promote capacity to provide informed consent, by allowing potential participants time to develop an understanding of the research and discuss it with others, and several opportunities to withdraw interest. When I met with individuals at the final stage of this consent process, I remained conscious of coercion and thus focussed on ensuring they understood that I was not affiliated with their service, that a staff member had initially approached them only because I did not work there and could not enter the unit without assistance, and that non-participation (or participation) would not impact their treatment or detention.

On reflection, this concern was particularly pertinent given the sense of coercion to undertake DBT all participants highlighted and that could have influenced their agreement to participate. Indeed, within my reading around coercion while writing-up my research, I noted Adshead's (2003) discussion of the limited choices and control individuals in forensic settings have over their lives as extending to their involvement in research. I cannot be certain but would like to think that one participant at each site refusing involvement when first introduced to the study by staff, and a further two declining participation after initially expressing interest, reflects some sense of choice.

I did, however, notice some participants appeared keen to emphasise during interview how their risk had reduced due to attending DBT. Concerned that they still believed the interview would feed into their progression, or that they were trying to "please" me (Perry, 2004), I reiterated throughout interview the independence of myself and the research from their service, the confidentiality of interview data[1], and their position as the "expert". In this manner, I regarded informed consent as an ongoing process (Smythe & Murray, 2000).

[1] The boundaries of confidentiality relating to risk of harm were made explicit during the consent process.

Through guided exploration of capacity (Thomas & Stenfert Kroese, 2005), I felt confident participants understood and thus provided informed consent. Instead, I considered participants' presentations as reflecting their experience of professionals expecting them to evidence their risk-reduction, the power imbalance between them and myself, and the lack of trust these factors can create (Adshead, 2003). Indeed, it became apparent during and when transcribing interviews that through using my clinical skills to build rapport (Haverkamp, 2005), participants began describing their views of DBT and of their aggression more openly; perhaps rapport created faith that there genuinely would not be repercussions of their honesty.

I also noted increasing richness of participants' responses, with the initial pages of transcripts containing the most utterances of "don't know" and "can't remember". Instead of, or in addition to, reflecting reduced acquiescence and anxiety, this may have simply related to participants being unable to recall certain details, due to the time that had since elapsed since their attendance at DBT or their ID-related memory difficulties. Furthermore, high emotional arousal impedes formation of memories (Lane, Ryan, Nadel, & Greenberg, 2015), which may account for why participants appeared to find it most difficult to explain how they may have used DBT skills when highly aroused. These factors strengthen the recommendation made within my empirical paper for longitudinal research involving data collection over several points, to elicit participants' memories at the time and to track changes in perception (Thomsen & Brinkmann, 2009).

With interviews taking place within the secure units where participants were detained, I also considered whether location influenced disclosure by creating fear of criticising the service (Merriman & Beail, 2009) or enactment of a "restricted patient" identity, which in turn restricts openness (Elwood & Martin, 2000). However, after the initial hesitation discussed above, participants appeared to share their perspectives candidly; highlighting difficulties and distress "created" by DBT, some of which were attributed to staff. This

indicates that research participants in forensic settings can provide open and honest data, as similarly found by Knowles, Hearne and Smith (2015).

Location was dictated by security requirements; however, conducting interviews in the environment within which the processes under study were occurring provided context to and a richer understanding of data. Observing the physical and relational restrictions of the units offered insight into the lack of control and coercion central to the GT, for example, conducting some interviews in "quiet rooms" on the ward highlighted recognition by services that its users need a safe space to retreat. However, this was still within the boundaries of staff control, with these rooms being glass "fishbowls" to enable observation of occupants. Furthermore, during one interview, I could hear another service user screaming and making banging noises. Concerned this would cause discomfort or at least distraction for my participant, I explored termination of the interview, yet her response—"She's always doing it, ignore her"—powerfully emphasised the desensitisation to displays of distress.

1.3.1 Personal conflicts

If PFID are inescapably situated within highly emotive environments, they surely face greater challenges to emotional regulation (Hogue et al., 2007), perhaps creating a much greater task/test of managing their emotions than that faced by the professionals responsible for judging their risk. As such a professional working within a (non-ID) forensic service, this reflection has increased my empathy and led me to more frequently encourage my colleagues to consider the impact of our setting on the service users we work with. My empirical findings also resonate with my motivations for working with people with forensic needs and/or with ID, which include my stance that they are as deserving, if not more so due to their often disadvantaged and traumatic personal experiences, of the support and care the rest of society can take for granted. However, the findings also forced me to actively contemplate a number of conflicts I have avoided fully connecting with over the years.

The first of these is that the interventions provided to PFID, such as DBT and those examined within my systematic review, largely focus on the encouraging the individual to address their thoughts, feelings and behaviour. This approach can be regarded as locating the problem within the person and dismissing their wider context and the injustices, oppression and abuses they might face through, for example, exclusion and exploitation (James & Stacey, 2013). With such experiences, who would not experience distress or feel angered? While I believe that in a more just and inclusive society many individuals would not require forensic services, pragmatically we have to currently intervene at *both* the individual and societal level.

I am also not discounting the need and benefit for some individuals to be detained in forensic services and to undertake psychological interventions. Indeed, my participants acknowledged their past behaviour as having caused serious harm and described their detention as the catalyst for wanting to cease aggression. Several attributed to DBT their pride in now being able to have their voice heard and needs met without aggression, and of developing a sense of belonging, increased self-esteem and positivity for the future that they had not previously experienced. However, my empirical research has made me recognise how the benefits achieved by my participants involved and caused significant stress and distress along the way. This has prompted a number of discussions with colleagues in my workplace, and a repeated focus within my clinical supervision, around how we can reduce or eliminate these costs of progress and support rather than coerce. This, like societal change, is a work in progress; however, I feel confident that paying attention to these issues and encouraging other staff to be similarly mindful is a good starting point. In the coming months, I shall be disseminating my empirical findings to my research sites and participants, and through publication, but also to DBT trainers and new facilitators as I shall be attending

DBT training myself. I hope this growing awareness facilitates similar attempts to address the distress and coercion highlighted by my research.

Prior to this research I was not oblivious to the coercive nature of psychological interventions in forensic settings, for example, I have known individuals serving prison sentences be refused parole as they have not completed therapy. I believe I rationalised this coercion, and my involvement in it, by aligning myself to the argument that the skills learnt ultimately enrich lives, and through witnessing significant improvements in self-esteem, confidence, emotion regulation and interpersonal functioning. I regarded interventions such as DBT as effective, and while I still do, I was not aware of the mechanisms underlying the change I observed, how harmful these can be, nor how coercion can exist at all stages of intervention, not just at the point of agreeing to undertake treatment. My reason for utilising GT as my methodology was to identify these mechanisms of change, rather than to more simply find out "does DBT work?"

I saw GT initially a means to an end; a tool that would let me reach my research aim in a way that did not conflict with my epistemology. I experienced a number of initial challenges to using this methodology, including the substantial data coding to perform, ensuring I was not relying purely on description but exploring at a deeper level what was going on for my participants and why, and then developing from this a model that captured the complexities but still would make sense to someone not as immersed in the data as myself. As well as my unfamiliarity with GT, these difficulties were most certainly exacerbated by the worries I had around accessing participants and subsequently submitting my thesis late, but I was assisted in overcoming these challenges by my academic supervisor, whose knowledge of GT provided both reassurance and guidance. Once all interviews were complete and this pressure alleviated, I came to appreciate how invaluable GT methodology was in enabling recognition and understanding of the deeper, underlying process of what

worked for my participants and why, the context within which this occurred, and the factors that facilitated or inhibited change (Matthews, 2014).

I also recognised how GT was not just compatible with my epistemological position but allowed me to remain true to it while further developing my stance, which can be summarised as "Knowledge is…socially constructed, but it is knowledge about something, about a layered, differentiated reality" (Hockey, 2010, p. 366). I regard my participants' experiences of coercion and distress as very real for them, and the use of constructivist GT in my research "addresses human realities" (Charmaz, 2000, p.523) while contributing towards evidence-based practice by assessing what works in DBT for PFID, furthering professional accountability, and encouraging and enhancing change (Oliver, 2012).

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Chapter 4 : Ethics Section

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Doctorate in Clinical Psychology

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Integrated Research Application System (IRAS) ethics application form submitted for NHS Research Ethics Committee (REC) approval

NHS REC Form | Reference: 15/NW/0654 | IRAS Version 4.0.0

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select "Save" and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Adapting Dialectical Behaviour Therapy: What Works? v.1

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
(•) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (•) No
b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (•) No
c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (•) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland
[ ] Wales
[ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (●) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(●) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

( ) Yes (●) No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

6. Do you plan to include any participants who are children?

( ) Yes (●) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (●) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
The project is being undertaken as part of the Chief Investigator's Doctorate in Clinical Psychology.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

NHS REC Form | Reference: 15/NW/0654 | IRAS Version 4.0.0

Integrated Research Application System
Application Form for Research involving qualitative methods only

NHS Health Research Authority

Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Adapting Dialectical Behaviour Therapy: What Works? v.1

Please complete these details after you have booked the REC application for review.

REC Name:
North West - Liverpool Central

REC Reference Number:
15/NW/0654

Submission date:
27/07/2015

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Working title: Adapting Dialectical Behaviour Therapy for clients in a forensic learning disability service: A qualitative study of 'what works'.

Service user information title (more accessible/basic language): Adapting Dialectical Behaviour Therapy (DBT): What works?

A2-1. Educational projects

Name and contact details of student(s):

Student 1

Title	Forename/Initials	Surname
Miss	Claire	Browne

Address: Division of Health Research, Faculty of Health & Medicine
Furness College, Lancaster University
Lancaster
Post Code: LA1 4YG
E-mail: c.browne@lancaster.ac.uk

Telephone	07411532256
Fax	01524592401

Give details of the educational course or degree for which this research is being undertaken:
Name and level of course/ degree:
Doctorate in Clinical Psychology D.ClinPsy

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Ian	Smith
Address	Division of Health Research, Faculty of Health & Medicine		
	Furness College, Lancaster University		
	Lancaster		
Post Code	LA1 4YG		
E-mail	i.smith@lancaster.ac.uk		
Telephone	01524592282		
Fax	01524592401		

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Miss Claire Browne	☑ Dr Ian Smith

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- (●) Student
- ( ) Academic supervisor
- ( ) Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Miss	Claire	Browne
Post	Trainee Clinical Psychologist		
Qualifications	BSc (Hons) Psychology, MSc in Forensic Psychology, currently working towards a Doctorate in Clinical Psychology (D.ClinPsy)		
Employer	Lancashire Care NHS Foundation Trust		
Work Address	Division of Health Research, Faculty of Health & Medicine		
	Furness College, Lancaster University		

	Lancaster
Post Code	LA1 4YG
Work E-mail	c.browne@lancaster.ac.uk
* Personal E-mail	claire_browne@hotmail.co.uk
Work Telephone	01524 592971
* Personal Telephone/Mobile	07411532256
Fax	01524592401

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Ms	Debbie	Knight
Address	Research Support Office		
	B58 Bowland Main		
	Lanacaster University		
Post Code	LA1 4YT		
E-mail	ethics@lancaster.ac.uk		
Telephone	01524 592605		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	
Sponsor's/protocol number:	n/a
Protocol Version:	3
Protocol Date:	03/07/2015
Funder's reference number:	n/a
Project website:	

Additional reference number(s):

Ref.Number Description	Reference Number
n/a	n/a

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, this summary will be published on the website of the National Research Ethics Service following the ethical review.*

A number of forensic mental health services worldwide are delivering dialectical behavioural therapy (DBT) skills groups for service users who have intellectual disabilities (ID) to help them develop skills for managing their emotions. However, as DBT is a manualised intervention that employs quite complicated terminology and mnemonics and requires its group members to complete regular written homework tasks, significant adaptations have to made by the services delivering this skills group to ID service users. Despite a growing evidence base suggesting that DBT groups that have been adapted for the ID population are effective, there is no research or evidence-based guidance that clarifies what adaptations should be made and why. If each service makes different adaptations to the DBT groups they deliver, it is very difficult to reach conclusions about how effective DBT for forensic service users with ID actually is.

This study will recruit forensic secure mental health service users with an ID who have attended or are attending an adapted DBT skills group. Participants will attend a semi-structured interview expected to last between twenty minutes to one hour, during which they will be asked about their experiences of attending the adapted DBT skills group, with a focus on what was helpful or less helpful for them. In gathering these service user perspectives, this study will aim to fill the gap in the current literature base by generating a greater theoretical understanding of which aspects of the DBT intervention adapted for a forensic ID population are experienced by service users as working for them and how. This may help clinicians to make evidence-based decisions on what adaptations are beneficial to apply to DBT interventions for forensic ID service users, and may inform the development of new adaptations as well as teaching and training for staff.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

RECRUITMENT:
Potential participants will be invited to express interest in the study through accessible written communication complemented with visual aids, which will clearly
state that choosing to participate or to decline involvement will not affect the care they receive. At this point, the Chief Investigator will have no access to the personal data of potential participants. The initial point of contact for enquiries regarding the study will not be provided by any member of the research team so as to prevent real or perceived coercion. All study materials will clearly state that participation (or otherwise) in the study, or choosing to 'drop out' from the study at a later point, will not affect the care they receive from their service, and no incentives for participation will be given. All participants will be treated in accordance with the ethical guidelines of the British Psychological Society (BPS), Health Care and Professionals Council (HCPC), and Lancaster University.

CONSENT & CONFIDENTIALITY:
In brief, informed consent will be sought from all potential participants, and no person will be permitted to take part in the study without providing informed consent. The sample of participants drawn from the forensic secure service population will include individuals who have mental health difficulties and a learning disability. The provision of informed consent is paramount, and the Chief Investigator will be careful to thoroughly explain to participants, using accessible terminology, all aspects of the study in order to ensure that they understand what will be asked of them. Similarly, all study materials have been written using basic familiar language and pictorial aids with terminology avoided or explained to clearly set out the purpose of the study, what will be expected of participants, and the (lack of) ramifications for nonparticipation or for withdrawal. The Chief Investigator seeking informed consent is experienced in working with individuals with intellectual disabilities, and will be conducting an assessment of each participant's capacity to consent to take part in interview prior as part of the process of gaining consent. With participants having an intellectual disability, there will potentially be issues raised in respect of their capacity to consent to taking part in the research. It will therefore be the responsibility of the Chief Investigator to ensure that informed consent is obtained from all participants. The Mental Capacity Act (2005) will be utilised where required, specifically Section 32 guidance for

identifying a consultee as necessary will be adhered to. In addition, the Chief Investigator has familiarised herself with the guidance for the
Mental Capacity Act compiled by the British Psychological Society and will be mindful of the need to minimise the risk of coercion and socially desirable responding throughout this process. If after this assessment there remains any doubt over a potential participant's capacity, clinical and academic supervision shall be sought before conducting the interview is considered.

In conducting research within forensic secure settings, the right to confidentiality must be balanced with the nature of the environment and the duty of care
of the service. Before providing informed consent, participants will be informed that their information will remain confidential, with the exception of the participant providing information regarding immediate risk to their own safety, the safety of another individual, or the security of the service. Participants will be duly informed on any occasion when the researcher will break confidentiality for these reasons.

RISKS, BURDENS, AND BENEFITS:
Whilst there are no risks anticipated with participating in this study, these factors have been explored with the Chief Investigator's academic and field supervisors, and a number of considerations shall be held in mind. Firstly, although it will be emphasised that participation will not impact on their care/interviews will be kept confidential etc., it is possible that participants may feel uncomfortable discussing their experiences whilst still residing within the service where they accessed the DBT skills group. This will be discussed with participants, and they will be reminded that the study is in no way related to their involvement with the service and every precaution will be taken to ensure that the all participants feel safe, comfortable, and aware that they have the freedom to withdraw from the study without repercussion should they wish to do so.

It is recognised by the Chief Investigator that they will be exploring participants' experience, and whilst no interview questions will require sensitive disclosures, it is still possible that this could occur, and every care will be taken to ensure that the participants' dignity and rights are not compromised or abused. Participants will be verbally reminded by the Chief Investigator at the end of their interview, as well as being provided with an accessible debrief sheet, of sources of support should the study cause upset or distress. This study has strict protocols in place in the event of this occurring. Participants will be offered the option of pausing the interview and taking a break, or discontinuing the session if they choose to. The interview or participation in the study may be discontinued and consent may be withdrawn by either the Chief Investigator or participant at any time if it is deemed too distressing for the individual. If the Chief Investigator has concerns over the wellbeing of a participant, they will inform the participant, discuss this with them, and collaboratively consider appropriate referrals or avenues of support. Similarly, participants will also informed that taking part in the study will be of no immediate benefit, but may benefit future service users attending DBT groups.

The risks to the Chief Investigator have also been considered, and specific protocols, including Lancashire Care NHS Foundation Trust's Zero Tolerance to Violence Policy and Guidelines, will be adhered to at all times throughout the study.

A6-3. Proportionate review of REC application *The initial project filter has identified that your study may be suitable for proportionate review by a REC sub-committee. Please consult the current guidance notes from NRES and indicate whether you wish to apply through the proportionate review service or, taking into account your answer to A6-2, you consider there are ethical issues that require consideration at a full REC meeting.*

○ Yes - proportionate review ◉ No - review by full REC meeting

Further comments (optional):

Note: This question only applies to the REC application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation

- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The primary aim of this research study is to develop a model, based on service user perspectives, which will offer a greater theoretical understanding of the effectiveness of the adaptations made to DBT skills groups for a forensic ID population.

The research question therefore asks what aspects of the adapted DBT intervention are experienced by forensic ID service users as working for them and how.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

This generation of a clinically relevant theory about adapted DBT for the forensic ID population by this study will facilitate comparison with the current theoretical understanding of 'standard' DBT. This may help clinicians ascertain what adaptations are beneficial to apply to DBT interventions for forensic ID clients, or may inform the development of new adaptations as well as teaching and training for staff.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Dialectical Behaviour Therapy (DBT) is a comprehensive psychological intervention that was first developed as an outpatient treatment for individuals with a diagnosis of Borderline Personality Disorder (Linehan, 1993). The central tenet of DBT is that individuals who experience significant problems with aggression, depression, substance abuse, self-harm and impulsivity engage in these self-destructive behaviours in a maladaptive attempt to manage their emotions. DBT interventions use an integrated model combining a range of cognitive and behavioural approaches with aspects of Eastern philosophy (including mindfulness), and typically consists of individual therapy, group skills training sessions, and weekly team meetings of all therapists where clients are discussed. DBT has been empirically validated as an effective form of treatment for Borderline Personality Disorder, which reduces suicidal ideation, self-injurious behaviours and length of inpatient stays (Koons et al., 2001; Linehan et al., 2006; Linehan et al., 2002; Linehan et al., 1999; Rizvi & Linehan, 2001; Verheul et al., 2003). DBT interventions have also shown to reduce the overall costs associated with mental health treatment (Aos, Lieb, Mayfield, Miller, & Pennucci, 2004), and may ameliorate staff burnout (McCann, Ball & Ivanoff, 1996).

While personality disorder is known to be at least as prevalent in populations with intellectual disabilities (ID) as in other groups (Alexander & Cooray, 2003; Morrissey & Hollin, 2010), few studies have reported use of DBT with clients with ID. This is despite a number of reasons to consider DBT to be of relevance for this population, including DBT's acceptance-based, positive, validating and person-centred approach which is consistent with values important for working with individuals with ID (Department of Health, 2003). Furthermore, DBT is a supportive skills-based intervention which uses behavioural approaches that have a well-established evidence base in ID (Sturmey, 2005), cognitive approaches that have some evidence base in ID (Taylor, Lindsay, & Wilner, 2008), and incorporates aspects of social skills training, with ID individuals often lacking interpersonal skills (Morrisey & Ingamells, 2011).

Of those studies that have reported on the use of DBT, or components of DBT such as mindfulness training, with ID individuals, positive outcomes have been noted, including reductions in aggression and risk-taking behaviour (Brown, Brown, & DiBiasio, 2013; Chapman, Hare, Caton, Donalds, McInnis, & Mitchell, 2013; Esbensen & Benson, 2003; Harper, Webb, & Raynor, 2013; Lew, Matta Tripp-Tebo & Watts, 2006; Mavromatis, 2000). Such outcomes, coupled with the increasing use of DBT within forensic settings (e.g., Evershed, Tennant, Boomer, Rees, Barkham, & Watson, 2004; McCann, Ball & Ivanhoff, 2000; Warren et al., 2003), have led to DBT interventions being introduced for ID clients in secure forensic services (Morrisey & Ingamells, 2011; Sakdalan, Shaw, & Collier, 2010). This small number of

studies have shown promising preliminary results, including decreases in the level of risks and challenging behaviours, and reinforcing DBT as a habilitative intervention that is useful in addressing the complex presentations and needs of the forensic ID population.

The delivery of DBT to the ID client group requires significant adaptations due to the complexity of DBT terminologies, the large number of target skills to be acquired and the reliance on complicated mnemonics to assist with such learning, the lengthy duration of DBT sessions, and the emphasis on handouts and completion of homework requiring a high level of literacy. The aforementioned studies which reported on their use of DBT with forensic ID clients highlight such issues and the steps taken to try and bridge this gap. In doing so, Morrisey and Ingamells (2011) comment on how such adaptations could lead to a reduction in treatment integrity due to unintentional drift from the underpinning theoretical model of DBT. With services across the world attempting such adaptations, a lack of standardisation of DBT interventions for ID clients also make outcome generalisations difficult and preclude conclusions on 'what works' in respect of such adapted interventions.

Consequently, this study aims to fill the gap in the current literature base by generating a greater understanding of which aspects of the DBT intervention adapted for a forensic ID population are experienced by service users as working for them and how. Such focus on the individual's experience is lacking in the existing literature, therefore, research employing a qualitative methodology will start to address this deficit by enabling the exploration of the experiences and perspectives of adapted DBT service users. In doing so, this study will meet the call for researchers to go beyond global measures when seeking feedback from service users (Francis Report, 2013).

Given the current lack of knowledge in the literature, it appears vital that research begins to generate theory about the effectiveness of the adaptations to DBT for the forensic ID population, rather than merely testing out hypotheses which have been logically deduced from existing theory using quantitative methods (Glaser & Strauss, 1967). As such, the qualitative methodology of Grounded Theory shall be utilised to generate a clinically relevant theory about adapted DBT for the forensic ID population, which can be compared with the current theoretical understanding of 'standard' DBT. This may help clinicians ascertain what adaptations are beneficial to apply to DBT interventions for forensic ID clients, or may inform the development of new adaptations as well as teaching and training for staff.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

The study aims to recruit no less than 10 and no more than 20 participants who will attend one interview expected to last between 20 minutes to one hour. The
duration of the study from commencement of data collection is estimated at nine months (including the write-up period).

To attempt to answer the proposed research question, the Chief Investigator will utilise a qualitative research design to explore and develop insight into what aspects of attending an adapted DBT skills group are experienced as helpful by forensic service users with an intellectual disability (ID). Qualitative studies allow researchers to explore behaviours, perspectives, feelings, and experiences in depth, and to understand the quality and complexity of a situation, using a holistic framework (Holloway & Wheeler, 2002). In practice, the formal systematic approach of quantitative research would not be suitable to gain the information this study hopes to acquire. The Chief Investigator chose a qualitative design for the study as it facilitates the precise actions the Chief Investigator aims to achieve, such as identifying what was helpful or less helpful for ID service users attending a DBT skills group and why.

Recruitment: Following ethical approval, potential participants will be identified using the inclusion criteria outlined in the Target Sample section above by the field supervisor. This study will employ purposive sampling whereby all service users who meet the inclusion criteria will be considered for the opportunity to engage in the study.

Those service users meeting the inclusion criteria shall initially be approached by their key worker due to this being a person with whom they are familiar but who is not involved in the research so as to avoid coercion. The key worker will have been briefed on the aims of the research and provided with sufficient information about the study to be able to explain its aims and the requirements and rights of the participants in accessible language. The key worker shall also provide potential participants with a Participant Covering Letter and Participant Information Sheet (PIS), written in accessible language and using visual aids to clearly detail the aims of the study and rights of the participants, for example, that choosing to not to participate will have no impact on the care they receive. The potential participant will be given one week to consider whether they are interested in taking part, after which they will be revisited by their key worker who can answer any further questions they may have and remind them of their rights. If the potential participant indicates that they may like to take part, they will be asked to sign the reply slip and enclose it in the envelope provided before passing it to a staff member. The reply envelopes shall be collected by a member of the research team and passed to the Chief Investigator.

On receipt of the signed reply slips, the interested potential participants will then be approached by a member of the site research support team who can again answer any further questions regarding the study, and if the potential participants remain interested, arrange a time for the Chief Investigator to attend to complete the interview.

If any participant withdraws their consent to take part in the study, additional participants shall be recruited into the study using the method detailed above.

If difficulties are encountered with securing a sufficiently large population of potential participants due to study sites withdrawing their collaboration, the study could instead recruit from staff members who deliver the adapted DBT skills groups to develop a model of what adaptations they view, from their practical experience, as working well or otherwise for the forensic ID service users. This would still meet the aim of the study but focus not on service user experience but the experience of DBT skills facilitators. If this approach is instead taken, the invitation to participate in the study and participant information sheet would be emailed by the field supervisor to all staff who deliver DBT skills groups at each site. This email would provide the Chief Investigator's university email address and ask any staff interested in participating to express this by emailing the Chief Investigator. The Chief Investigator would then reply and open a dialogue about the study in which the PIS would be discussed, any questions could be answered, rights to decline participation or withdraw after consenting to participate reiterated, and a time to arrange to meet to discuss and provide consent and conduct the interview arranged. Interviews would take place at the staff participant's work place (study site) at a time convenient for the staff member.

Data collection: This study shall utilise face-to-face, flexible, semi-structured interviews as the method of data collection, guided by the Grounded Theory research design. All interviews shall take place at the forensic secure service where the participants reside in a private interview room. An initial interview guide will be used to explore 'what works' in adapted DBT with a forensic ID population, in which a few pre-determined questions using accessible language will be asked of the participants, and then elaborated upon/explored in line with their responses. The interview guide will then be updated and become more focussed after each interview to include additional areas of interest raised which will be explored with subsequent participants. The interview guides will form a point of departure (Charmaz, 1995) to help observe the data, generate new ideas and think analytically. As such, not all participants will be asked all of the questions, and the interview process will be guided by participants' responses.

The Chief Investigator shall meet with the participants at the time arranged between the participant and site support member to revisit the study aims and PIS, highlight their rights, answer any questions, and ask the participant to sign the Consent Form. The interviews will be recorded via a Dictaphone and last approximately 20-60 minutes. Following completion of the interview, participants will be fully debriefed, provided with a Debrief Sheet, and advised that a summary of the study's key findings will be made available upon completion of the research.

To ensure confidentiality throughout the process, participants will allocated pseudonyms by the Chief Investigator. The field supervisor will not have
access to the raw data due to this pertaining to the service within which they work.

Withdrawal from study: In accordance with guidance from the British Psychological Society, all potential participants will be advised initially by the Participant Information Sheet and Informed Consent sheet, and then by the Chief Investigator prior to and immediately after the interview, that they are free to withdraw their participation from the study without consequence: it will be clearly stated that there will be no impact on the care they receive from their service and that their legal and medical rights will not be affected. Participants will be advised that any data collected at this stage will be destroyed should they choose to withdraw from the study. Participants will have also been advised that once their data has been anonymised and entered the writing-up for publication stage, extraction may be more difficult, though every attempt will be made, up to the point of publication.

Analysis: The Chief Investigator will use Grounded Theory (GT) to analyse the collected data, using Charmaz's (2006) GT guidance. The study will then be written up as a journal article for submission.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [x] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Members of the REACT self-advocacy group, all of whom have a learning disability, have provided consultancy in respect of the research design and in the creation of all study materials. Their recommendations have been reflected on and implemented to enrich the study's quality and accessibility. REACT have gained an impressive reputation and credentials as an organisation led by people with learning disabilities that serves communities, partnership Boards and statutory services wishing to improve the delivery and accessibility of their services by including people with disabilities in decision making processes.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

The researcher intends to employ a Grounded Theory guided form of purposive sampling – theoretical sampling - whereby potential participants meeting the inclusion criteria below shall be recruited and the sampling process guided by the ongoing theory development, until data saturation is achieved or time restraints prohibit further data collection. Capacity to consent to interview shall be assessed by the researcher immediately prior to the interview.

Inclusion criteria:
- English speaking
- Service users who have attended and completed an ID-adapted DBT skills group (or if staff are recruited, staff members who have delivered / are delivering a DBT skills group).
- Service users who began attending an ID-adapted DBT skills group but 'dropped out' after three sessions.
- Service users who are currently attending an ID-adapted DBT skills group and have attended a minimum of three sessions.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

With the service users having all participated in an ID-adapted DBT skills group requiring, for example, group discussions and the completion of homework, no communication issues are foreseen in respect of potential participants engaging in a one-to-one interview with an interviewer experienced in communicating with people with intellectual disabilities. However, discussions will be held with each individual's key worker to identify any specific communication adaptations that would be advantageous to employ, along with any changes to the individual's ability to participate in the research, such as the commencement of a new medication or having sustained a head injury. Each potential participant's consultant psychiatrist shall also be informed of the individual's expressed interest in taking part in the research and be asked to state whether they regard the individual as being unable to participate.

Exclusion criteria:
- Service users who are deemed unable to participate in interviews by their key worker/consultant psychiatrist.
- Service users who are deemed unable to provide consent to interview following a assessment of their capacity to do so by the researcher.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4

Initial invitation to participate in the research study.	1 - 20 minutes	The research site field supervisor shall identify potential participants meeting the inclusion criteria and ask their key workers to provide them with the Study Introductory Sheet and Participant Information Sheet and briefly discuss the study aims and answer any initial questions. Recruitment: 10-20 participants. Location: In a private room at the forensic secure service service study site.
Answering questions regarding the invite to participate in the study.	1 - 20 minutes	A member of research support team based at the research site shall visit potential participants to answer any questions and revisit their rights to participate/decline.Recruitment: 10-20 participants. Location: In a private room at the forensic secure service study site.
Arranging interview.	1 - 10 minutes	After the Chief Investigator has received a signed reply slip, they shall ask the potential participants' key workers to arrange an interview slot at a time convenient for the participant. Recruitment: 10-20 participants. Location: Forensic secure service study site.
Revisiting Participant Information Sheet and assessing capacity to provide informed consent.	1 - 20 minutes	The Chief Investigator. Recruitment: 10-20 participants. Location: In a private interview room at the forensic secure service study site.
Individual semi-structured interviews: one interview per participant	1 - 40 minutes	The Chief Investigator. Recruitment: 10-20 participants. Location: In a private interview room at the forensic secure service study site.
Debriefing of participants following interview.	1 - 10 minutes	The Chief Investigator. Recruitment: 10-20 participants.

A21. How long do you expect each participant to be in the study in total?

From initial contact to dissemination of findings, participants will be in the study for no longer than a total of nine months. Once participants express interest in taking part in the study, they will be invited to take part in their interview within one month.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Whilst no potential risks of burdens are anticipated for participants, the following Risk Management Protocol has been developed to account for any occurrences:

Potential risk:

Whilst participants will not be asked sensitive questions, their involvement in the interview process may result in a negative emotional reaction by participants and subsequently expressions of distress.

Preventative measures:

- After a participant has indicated their interest in participating in the study, the Chief Investigator will inform their Consultant Psychiatrist of their likely involvement in the study.
- Participants will be fully briefed prior to their interview using accessible language as to the aim of the study, their role within the research and what will be done with the data they provide by completing the interview.
- Participants will be informed that they are under no obligation to answer all of the questions asked by the interviewer.
- Participants will be informed that they can withdraw from the study at any point without detriment to themselves.
- Participants will be fully debriefed at the end of the interview, reminded of how and by whom their data will be handled and stored, and advised that a summary of the findings of the research will be made available to them upon its conclusion.
- Participants will be reminded that should they experience any distress after the interview, they should inform their

Case Manager, key worker, Consultant Psychiatrist or another staff member who will assist them in accessing appropriate support, or that they can request to use the telephone to contact other support agencies provided in their Debrief Sheet.
• Participants will be able to initiate contact with the Chief Investigator should they wish to ask questions relating to the study at a later date.

If the Chief Investigator deems a participant to be experiencing distress at any time during the interview, or if a participant reports that they are experiencing distress, they will be provided with the option to take a break or to end the interview. The participant's decision will be respected and their level of distress ascertained through interview and monitored if they choose to continue with the session.
• If the participant chooses to terminate their involvement with the interview, they will be reminded of the sources of support they can utilise as detailed in their Debrief Sheet. They will be returned to their residential area and staff informed that the participant requires monitoring. Their Case Manager and key worker shall also be informed of what has occurred, with the participant informed that this communication shall occur.

As part of their training as a Trainee Clinical Psychologist, the Chief Investigator is experienced in containing distress within face-to-face meetings such as these research interviews. The study's field supervisor will also be available for the Chief Investigator to seek advice from should a participant experience distress as a result of their involvement in the research.

Potential risk:

It must be acknowledged that some participants may have been detained following acts of violence. Therefore, action to be taken upon awareness of participant's potential for aggression have been considered. As the Chief Investigator has previously worked within both forensic secure services and the High Security Prison estate, she has experience in responding to such situations when faced with individuals who experience negative emotions and express these using aggression.
• If the Chief Investigator deems a participant as becoming aggressive at any time during interview, the Chief Investigator shall terminate the interview immediately and notify staff.
• If a participant reports that they are feeling agitated/aggressive during the interview, they will be provided with the option to take a break or to end the session. The participant's decision will be respected and their level of aggression will be ascertained through interview and monitored if they choose to continue with the session.
• If the participant chooses to terminate their involvement with the session, they will be returned to their residential area and staff, including their Case Manager and key workers, informed that the participant requires monitoring.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

A24. What is the potential for benefit to research participants?

Other than the potential for participants to experience some positive gains from having the opportunity and freedom to discuss their experiences of attending a DBT skills group, there will be no immediate benefit to the participants. Any benefits as a result of the study would be at a later date and for future DBT skills group service users, if the knowledge gained through the exploration of the research data can be used to improve current group delivery.

A26. What are the potential risks for the researchers themselves? *(if any)*

Whilst this study is not likely to expose the Chief Investigator to risk, a protocol has been designed for this eventuality. This include the debriefing of the Chief Investigator following data collection by the academic and field supervisors to explore any issues raised by the research.

As the Chief Investigator has been employed within forensic secure mental health services and by the Prison Service and currently works on a daily basis with intellectually disabled individuals detained under the Mental Health Act on a secure inpatient unit due to their challenging behaviour and risk of harm to self and others, the potential risks she could face are not above those she has and does face on a daily basis. There are no measures that will be required that will take the Chief Investigator out of their 'comfort zone' or away from standard practice and NHS policy.

All participant interviews will be conducted at the study sites where the participant resides. As the Chief Investigator is a doctoral student but the study sites are not under her university's control, the interviews constitute fieldwork. Therefore, the Chief Investigator will adhere in full to Lancaster University's Guidance on Safety in Fieldwork document and the

Lancashire Care NHS Foundation Trust Lone Working Policy, taking all reasonable care to protect herself and implement the 'vet, vigilance, and verify' personal safety guidelines set on in Appendix A of the Lone Working policy and within university guidance. Prior to any interview, the Chief Investigator will complete the risk assessments and checklists set out in Appendices A, C & D of the Lone Working policy and using the University Generic Risk Assessment Form, raising any issues with her supervisors, and an interview will not be conducted if there are any known risk concerns. Immediately prior to conducting the interview, the Chief Investigator will use the checklist found in Appendix B of the Lone Working policy to ensure all foreseeable safety precautions have been taken. The Chief Investigator shall also discuss and adhere to the safety protocols individual to each study site with her field supervisors, and will also display her NHS ID badge at all times.

The Chief Investigator will terminate the interview if she feels at risk at any time, and report these concerns and any other potential risk issues to her supervisors and through the IR1 reporting system. The Chief Investigator has read and will adhere to the Lancashire Care NHS Foundation Trust's Zero Tolerance to Violence Policy and Guidelines, and has received training on breakaway, de-escalation, personal safety/security techniques and verbal and nonverbal communication skills.

As the interviews are being conducted at secure mental health services, which require visitors such as the Chief Investigator to sign in and pass through security checks, and for a member of staff to escort the Chief Investigator to escort the Chief Investigator to and from the interview room and for staff to be present in the vicinity, an external buddy system is not deemed necessary for this study as a member of staff will always be aware of the Chief Investigator's location.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

The research site's field supervisors will identify a list of potential participants meeting the following inclusion criteria:
- Service users who have attended / are attending a DBT skills group
- Are English speaking

Once a list has been compiled, those service users meeting the inclusion criteria shall initially be approached by their key worker who will explain the study aims and the requirements and rights of the participants in accessible language, and provide this information in written format also via the Participant Covering Letter and Participant Information Sheet (PIS), both written in basic familiar language and complimented by visual aids. The potential participant will be given one week to consider whether they are interested in taking part, after which they will be revisited by their key worker who can answer any further questions they may have and remind them of their rights. If the potential participant indicates that they may like to take part, they will be asked to sign the reply slip and enclose it in the envelope provided before passing it to a staff member. The reply envelopes shall be collected by a member of the research team and passed to the Chief Investigator.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

(●) Yes ( ) No

Please give details below:
The research site's field supervisor, who are members of the service's clinical care team, will access the site's DBT database to identify those service users who have attended or are currently attending a DBT skills group and thus fulfil the inclusion criteria. The Chief Investigator will have no access, at any point during the study, to service user records.

A27-4. Will researchers or individuals other than the direct care team have access to identifiable personal information of any potential participants?

( ) Yes (●) No

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Those service users meeting the inclusion criteria shall initially be approached by their key worker due to this being a person with whom they are familiar but who is not involved in the research so as to avoid coercion. The key worker will have been briefed on the aims of the research and provided with sufficient information about the study to be able to explain its aims and the requirements and rights of the participants in accessible language. The key worker shall also provide potential participants with a Participant Covering Letter and Participant Information Sheet (PIS), written in accessible language and using visual aids to clearly detail the aims of the study and rights of the participants, for example, that choosing to not to participate will have no impact on the care they receive. The potential participant will be given one week to consider whether they are interested in taking part, after which they will be revisited by their key worker who can answer any further questions they may have and remind them of their rights. If the potential participant indicates that they may like to take part, they will be asked to sign the reply slip and enclose it in the envelope provided before passing it to a staff member. The reply envelopes shall be collected by a member of the research team and passed to the Chief Investigator.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Each potential participant will be approached by their key worker as detailed in A29, and will have the study explained verbally and be provided with relevant clear and written information about the study. The potential participant will be given the opportunity to ask questions about the research study and will be given one week to consider the information sheet and decide if they want to take part.

On receipt of the signed reply slips indicating interest in taking part in the study, the interested potential participants will be approached by a member of the site research support team who can answer any further questions regarding the study, and if the potential participants remain interested, arrange a time for the Chief Investigator to attend to complete the interview.

The Chief Investigator will then arrange to meet with the potential participants who have expressed their interest in taking part in the study, to discuss the study further and if the participant feels comfortable to do so, and is assessed by the Chief Investigator as having the capacity to do so, provide informed consent. The Chief Investigator is experienced in consenting individuals in secure settings, especially in relation to assessing an individual's capacity to consent. The Chief Investigator will ensure that no sense of coercion is perceived by potential participants, that they fully understand what the study is about, what their participation consists of, who may have access to their data, how any data will be used and reported and how the final results of the study will be made available. Given the unique problems of gaining consent in a secure setting, extra emphasis will be given to the potential participants' rights to consent/not to consent and also their right to withdraw at any time, without the need to give a reason for doing so, free of any coercion or negative consequences/access to services or privileges.

The Chief Investigator is a Trainee Clinical Psychologist who has worked with individuals with intellectual disabilities and/or detained under the Mental Health Act for over nine years, and has developed competence in communicating information in a clear manner, whilst noting any issues such as capacity, distress, ambivalence, and uncertainty when conversing. The Chief Investigator will also access regular supervision from her supervisors, who are all Chartered Clinical Psychologists, during which consent and capacity issues shall be discussed.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

(●) Yes ( ) No

A31. How long will you allow potential participants to decide whether or not to take part?

Potential participants will be given one week to consider whether or not to take part in the study.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

The study will exclude those who might not adequately understand verbal or written information given in English as funds are not available to provide translators/interpreters. Their exclusion is therefore necessary, firstly due to the Chief Investigator wishing to understand the participant's experiences through a face-to-face spoken interview, and secondly, as during the interview an individual may pose a risk which is not able to be conveyed to the Chief Investigator.

The study's target participant population is individuals with intellectual disabilities (ID), therefore, adjustments to communication are vital. All written materials have been developed in line with Mencap's 'Make it Clear' Easy Read guidance (2009) and their accessibility reviewed by a self-advocacy group of individuals with ID. The Chief Investigator has experience in working clinically with and assessing/interviewing individuals with ID and is currently working with inpatients with severe communication and learning disabilities. Drawing on this experience, and that of the study's academic and field supervisors who all work with adults with ID, the interview shall be conducted so as to be accessible to any service users who choose to participate.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

(●) The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

( ) The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

( ) The participant would continue to be included in the study.

( ) Not applicable – informed consent will not be sought from any participants in this research.

( ) Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

☐ Access to medical records by those outside the direct healthcare team

☐ Electronic transfer by magnetic or optical media, email or computer networks

☐ Sharing of personal data with other organisations

- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☑ Use of audio/visual recording devices
- ☑ Storage of personal data on any of the following:
  - ☐ Manual files including X-rays
  - ☐ NHS computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☑ Laptop computers

Further details:
As potential participants reside at one of the study sites, no personal addresses or contact details are required. Each reply slip will, within the Header, have the study site initials (i.e., reply slips given to potential participants at [redacted] in the header) so that the Chief Investigator will know at which study the potential participant resides and where to contact to arrange the interviews.

With the participants' permissions, all interviews will be audio recorded. Following completion of an interview, the Chief Investigator will save the recording electronically on a secure server, and password protect and encrypt it. The original audio-recoding on the recording device will be deleted.

The research data e.g. interview audio recordings, interview transcripts, analysed data, demographic information collected, reply slips and Consent forms, will be saved as electronic data in password protected file space on the University secure server, and on an encrypted password protected laptop, by the Chief Investigator. Physical copies of the reply slips and Consent forms will be destroyed as soon as they are transferred to electronic format.

On completion of the study, the necessary electronic files, such as the participants' Consent forms, interview transcripts, and the coded data produced during analysis will be transferred securely to Lancaster University's Research Coordinator for storage in password protected file space on the university server for a period of ten years.

Anonymised direct quotations from participant interviews may be used in the reports or publications from the study, but no personal identifiable information will be attached to them.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

The Chief Investigator alone will have access to the participants' personal data, however, this will be anonymised using the procedure outlined in A37. The Chief Investigator's academic supervisor will have access to participants' raw and analysed data, but this will have been anonymised through the allocation of pseudonyms. Field supervisors will not have access to raw data due to participants being service users at their place of work.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The Chief Investigator alone will have access to the participants' personal data which shall be anonymised as soon as each interview is completed.

Storage and use of data after the end of the study

A43. How long will personal data be stored or accessed after the study has ended?

- ◉ Less than 3 months
- ○ 3 – 6 months

○ 6 – 12 months
○ 12 months – 3 years
○ Over 3 years

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◉ Yes ○ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

◉ Yes ○ No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
No suitable register exists for the registration of this research, as conducted by a Trainee Clinical Psychologist completing the study in part-fulfilment of a Doctorate in Clinical Psychology. A report of the research will be written up and submitted for publication. In the event of the report being accepted for publication, the abstract and/or full article will be available from the publisher's website.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity,

or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [x] Internal report
- [ ] Conference presentation
- [ ] Publication on website
- [ ] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [ ] Other (please specify)

A53. Will you inform participants of the results?

(•) Yes ( ) No

Please give details of how you will inform participants or justify if not doing so.
A summary report with adapted terminology will be made available to the participants of the study detailing the main findings, implications and recommendations.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- [ ] Independent external review
- [ ] Review within a company
- [ ] Review within a multi-centre research group
- [x] Review within the Chief Investigator's institution or host organisation
- [x] Review within the research team
- [x] Review by educational supervisor
- [ ] Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The scientific quality of the proposed study was reviewed by the Chief Investigator's academic supervisor, who is a Registered Clinical Psychologist experienced in conducting research, particularly qualitative studies. The study's proposal has also been subject to a peer-review process and scrutiny for approval by the Lancaster University Doctorate in Clinical Psychology Examination Board.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 20
Total international sample size (including UK): 0

Total in European Economic Area: 0

Further details:
A maximum of twenty participants will be recruited and interviewed within this study.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The Chief Investigator intends to acquire a purposive sample by recruiting from a population of service users who have attended or are currently attending a DBT skills group within a low/medium secure setting. Those participants who meet the inclusion criteria in full and none of the Exclusion Criterion and who consent to participate in the study will be included within the research sample, until sufficient numbers have been achieved for data saturation.

A power analysis is not required due to the use of qualitative methodology within this study. However, a larger number of participants than is usually recruited by qualitative studies will be sought due to this study's GT design. It is hoped that a sample of 15-20 participants will allow theoretical saturation to be achieved, whilst remaining feasible given the time and resource restrictions.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

To attempt to answer the proposed research question, the researcher has elected to utilise a qualitative research design to explore and develop insight into which aspects of an adapted DBT skills group its members found most helpful or otherwise. In contrast, the formal systematic approach of quantitative research, which incorporates numerical data to obtain information about the world (Burns & Grove, 2009), would not be suitable to gain the information this study hopes to acquire.

More specifically, the study will adopt a qualitative Grounded Theory (GT) design to inductively build a theoretical explanation of a social phenomenon (what aspects of adapted DBT are effective with a forensic ID population) based on the study data. The approach to GT will be informed by the original theory (Glaser & Strauss, 1967) but largely by the more recent contributions of Charmaz (2001, 2006).

Before the data is analysed, the Chief Investigator will transcribe all interviews verbatim by listening to the audio-recordings; this will be done in a private space to ensure participant confidentiality. The Chief Investigator will create Microsoft Word files for the interviews, all of which will be encrypted and protected by setting a password and made distinguishable by pseudonym. All files will be saved on Lancaster University's secure server.

Grounded Theory (GT)analysis will be used to analyse the transcript data, in line with the guidelines offered by Charmaz (1990, 2006) to ensure a clear, replicable, and transparent methodology. GT merges the processes of data collection and analysis. The researcher moves back and forth between gathering data and coding, and analysing it and then gathering more data. With this study fulfilling a doctoral research requirement, the data analysis will be guided by the Chief Investigator's academic supervisor, who is experienced in conducting and supervising GT research.

Initially, an interview will be undertaken with one participant. The Chief Investigator will transcribe each interview verbatim, with paraverbals and the Chief Investigator's impression of participant affect also included. This initial transcript will be 'incident to incident' coded line-by-line (Charmaz, 2006, p. 53) which will involve assigning codes to blocks of data within the transcript. These codes will then then amalgamated to form groups of codes which will be used to adapt the interview topic guide in accordance with principles of theoretical sampling. This process of adaptation will involve deciding which questions should be asked in the subsequent interviews to gather more data to define the initial codes. An interview will subsequently be undertaken with another participant and the analytic process repeated. An anonymised sample of this coding process shall be reviewed by the Chief Investigator's field supervisor to allow triangulation to occur.

The initial transcripts will be focused coded (coded with reference to the initial group codes) and some codes raised to conceptual categories. An initial model will then be developed with the aid of reflective notes and memos taken throughout the data collection and analysis. Further participants may then interviewed on the basis of theoretical sampling (selected in order to gather data which would add richness to the categories and themes and provide data to further populate the model). These final transcripts will be 'incident to incident' and focused coded with reference to earlier codes and conceptual categories, and all data collated to contribute to model formation.

The analysis may not reach a stage whereby no new codes are created, that is, data saturation. If this occurs, it is hoped that the study data will fit with the description of data 'sufficiency' provided by Dey (1999) in that existing

categories do not require revision or alteration in respect of new data.

The Chief Investigator will also record and explore her personal reflections on the study process. Reflecting on such experiences will enable acknowledgement of assumptions and biases within the data collection, analysis and theory generation.

Rigor:
Qualitative validity is to be determined through the use of strategies to check the accuracy of the findings. Validity will be captured through trustworthiness, authenticity and credibility (Creswell & Miller, 2000). Trustworthiness will be aimed for by the creation of an audit trail which will involve maintaining and preserving all transcripts, reflective notes, and coding documents. Authenticity refers to the reporting of each participant's experiences in such a way that it maintains respect for the context of the data and presents all perspectives equally so that the reader can arrive at an impartial decision. The Chief Investigator will also attempt to set aside their potential prejudices and biases using a technique called bracketing (Creswell, 2009). Purposeful sampling in this study will increase indepth understanding by selecting information-rich experiences from participants who have experienced a DBT skills group (Patton, 2002). Thick rich description will be achieved by presenting the participants' voices under each theme. This study will aim to achieve credibility by the Chief Investigator analysing the data through a process of reflecting, sifting, exploring, judging relevance and meaning, and ultimately developing themes and a theoretical model that accurately depict the experience of participants.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]

Post	[redacted]
Qualifications	[redacted]
Employer	[redacted]
Work Address	[redacted]
Post Code	[redacted]
Telephone	[redacted]
Fax	
Mobile	
Work Email	[redacted]

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]

Post	[redacted]
Qualifications	[redacted]
Employer	[redacted]
Work Address	[redacted]
Post Code	[redacted]
Telephone	[redacted]
Fax	
Mobile	[redacted]
Work Email	[redacted]

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]

Post	[redacted]
Qualifications	[redacted]
Employer	[redacted]
Work Address	[redacted]
Post Code	[redacted]
Telephone	[redacted]
Fax	
Mobile	
Work Email	[redacted]

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status:

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Debbie
Family name	Knight
Address	B58 Bowland Main, Lancaster University
Town/city	Lancaster
Post code	LA1 4YT
Country	UNITED KINGDOM
Telephone	01524592605
Fax	
E-mail	ethics@lancaster.ac.uk

Is the sponsor based outside the UK?

○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- ☐ Funding secured from one or more funders
- ☐ External funding application to one or more funders in progress
- ☑ No application for external funding will be made

What type of research project is this?

- ◉ Standalone project
- ○ Project that is part of a programme grant
- ○ Project that is part of a Centre grant
- ○ Project that is part of a fellowship/ personal award/ research training award
- ○ Other

Other – please state:

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	[redacted]	[redacted]	[redacted]

Organisation [redacted]
Address [redacted]
Post Code [redacted]
Work Email [redacted]
Telephone [redacted]
Fax
Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 14/09/2015
Planned end date: 16/11/2015
Total duration:
Years: 0 Months: 2 Days: 3

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England

☐ Scotland
☐ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study 3

Does this trial involve countries outside the EU?
○ Yes ◉ No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

☑ NHS organisations in England	3
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Social care organisations	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent hospitals	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	

Total UK sites in study: 3

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** In this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)
☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Lancaster University legal liability cover will apply for the [redacted] site which is a charity providing NHS care but not an NHS organisation.

Please enclose a copy of relevant documents.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site		Investigator/ Collaborator/ Contact	
Institution name	[redacted]	Title	[redacted]
Department name	[redacted]	First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		
Institution name	[redacted]	Title	[redacted]
Department name	[redacted]	First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		
Institution name	[redacted]	Title	[redacted]
Department name	[redacted]	First name/ Initials	[redacted]
Street address	[redacted]	Surname	[redacted]
Town/city	[redacted]		
Post Code	[redacted]		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

   - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
   - May be sent by email to REC members.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

(•) Chief Investigator

( ) Sponsor

- ○ Study co-ordinator
- ○ Student
- ○ Other – please give details
- ○ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Miss Claire Browne on 26/07/2015 12:10.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Lancaster University / Lancashire Care NHS Foundation Trust
Email:	c.browne@lancaster.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by An authorised approver at ethics@lancaster.ac.uk on 27/07/2015 09:49.

Job Title/Post:	Research Support Officer
Organisation:	Lancaster University
Email:	s.c.taylor@lancaster.ac.uk

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Ian Smith on 27/07/2015 09:23.

Job Title/Post:	Lecturer in Research Methods
Organisation:	Lancaster University
Email:	I.smith@lancaster.ac.uk

Appendices

Appendix A: REC favourable approval letter

NHS
Health Research Authority
National Research Ethics Service

NRES Committee North West - Liverpool Central
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 01616257818
Fax:

09 September 2015

Miss Claire Browne
Trainee Clinical Psychologist
Lancashire Care NHS Foundation Trust
Division of Health Research, Faculty of Health & Medicine
Furness College, Lancaster University
Lancaster
LA1 4YG

Dear Miss Browne

Study title:	**Working title: Adapting Dialectical Behaviour Therapy for clients in a forensic learning disability service: A qualitative study of 'what works'. Service user information title (more accessible/basic language): Adapting Dialectical Behaviour Therapy (DBT): What works?**
REC reference:	**15/NW/0654**
Protocol number:	**n/a**
IRAS project ID:	**182950**

The Research Ethics Committee reviewed the above application at the meeting held on 02 September 2015. Thank you for attending to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Carol Ebenezer, nrescommittee.northwest-liverpoolcentral@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

a. The Committee would like to see the Participant Information Sheet revised to
   i) Correct the information on page 5 re complaints where the words have separated
   ii) State that the recordings will be deleted after writing up
b. The Committee would like to see the Consent Form revised to
   i) Correct the spelling mistake (research) on page 2 point 5
c. The Committee would like to see the reply slip revised to use the same word consistently, study or research

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Summary of discussion at the meeting

The Chair welcomed you to the REC and thanked you for attending to discuss the study. The Committee told you that this was a very good study and applauded the inclusion of the REACT group in the design.

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)
The Committee asked what would be done if a participant became upset.

You said that you would discuss this with them if they were willing, and inform a member of staff, and tell the participant that you were doing so.

The Committee accepted this.

Informed consent process and the adequacy and completeness of participant information
The Committee thought that the Participant Information Sheet and Consent Form were good but requested minor changes as described in the decision below.

You said that one of the R & D sites had suggested you give the debrief sheet with the Participant Information Sheet and asked the Committee's opinion.

The Committee stated that it was more appropriate to give the debrief sheet after the interview, as stated in the application.

You stated that they had suggested not using the reply slip.

The Committee said that she should use it and see whether it worked. They also said that you should tell participants where to find it. You said it would be in the pack issued.

Other general comments
The Committee asked why staff were not being invited to take part to give data for triangulation.

You stated that the University had rejected this approach.

You said it had been suggested that you contact the MDT rather than just the clinical psychologist to check on the participant's capacity. The Committee agreed that this was a better approach.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [REC Covering Letter]	1	27 July 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Zurich Municipal - Employers liability insurance]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Zurich Municipal - Professional Indemnity Letter]		04 August 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Zurich Municipal - Public Liability Insurance Letter]		04 August 2015
GP/consultant information sheets or letters [Letter to consultants]	1	27 June 2015
Interview schedules or topic guides for participants [Thesis topic guide]	1	05 July 2015
Letter from sponsor [Sponsor letter]		21 July 2015
Other [Participant Reply Slip]	1	27 June 2015
Other [Participant Debrief Sheet]	2	27 June 2015
Other [University Guidance on Safety in Fieldwork]		
Other [Lancashire Care NHS Lone Worker Policy]		
Other [Clarification re 'Participant Covering Letter' and A54]	E-mail	30 July 2015
Other [Clarification re [redacted]	E-mail	14 August 2015
REC Application Form [REC_Form_29072015]	4.0.0	26 July 2015
Research protocol or project proposal [Thesis protocol]	3	03 July 2015
Summary CV for Chief Investigator (CI) [Claire Browne]		
Summary CV for student [Claire Browne]		
Summary CV for supervisor (student research) [Ian Smith]		16 April 2015
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Thesis Lay Summary]	1	27 June 2015

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports

- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/NW/0654	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Mrs Julie Brake
Chair

E-mail: nrescommittee.northwest-liverpoolcentral@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Ms Debbie Knight*
[redacted]

Appendix B: Research & Development department approval letter for 1st site

[redacted]
Research & Development Department
[redacted]

24th September 2015
Miss Claire Browne (DClinPsy student)
Division of Health Research,
Faculty of Health & Medicine
Furness College,
Lancaster University
Lancaster
LA1 4YG

Dear Claire,

Re: NHS Trust Permission to Proceed

Project: *Adapting Dialectical Behaviour Therapy: What Works?*

REC reference: 15/NW/0654

Protocol number: [redacted]: 2014-16-04**.** Lancaster University (not given).

IRAS project ID: 182950

Following the approval by NRES Committee North West - Liverpool Central Research Ethics Committee on 17th September 2015 and [redacted] Research & Development Committee on 18th August 2015, I am pleased to confirm that your proposed research study within [redacted] can proceed.

I would bring your attention to the responsibilities of researchers and yourself, Claire, as Chief investigator / Principal investigator required by this Trust in accordance with the Department of Health's Research Governance Framework. *All research conducted within this Trust must comply with the full requirements of the Research Governance Framework for Health and Social Care (www.doh.gov.uk) and fully adhere to the submitted project protocol approved by* [redacted] *and the relevant Research Ethics Committee (v.3 dated 3/7/15).*

This letter provides proof that the relevant Trust committees have formally reviewed your project and that the R&D Lead has formally approved your project. Members of staff from [redacted] are fully entitled to ask to see your formal letter of approval before they agree to allow you to access a ward or have any contact with other members of staff or service users or carers from the Trust.

Recruitment:

I note that, according to the SSI form (section 11), recruitment to this study will involve you liaising with the case managers / key workers on each ward, assisted by introductions through the [redacted] team. You will be assisted in this by [redacted] and field supervisor. Please do contact me should you wish to make any amendment to this recruitment plan.

Please note that, in line with national standards, it is good practice for you to recruit your first participant from [redacted] within 30 days of being granted Trust permission. Please do let me know the date of first recruitment to enable me to record the date of first recruitment as per national guidelines.

Monitoring & Reports

A representative from the Research Department will contact you to monitor the progress of your research within [redacted]. Please inform the department immediately of any proposed changes, amendments to or deviations from the ethics committee and research governance approved protocol.

On completion of the research, we request that you forward a copy of your final summary report so that your findings are made available to local NHS staff and to allow feedback to [redacted] R&D committee meeting.

On behalf of [redacted] I wish you every success for your research and I look forward to finding out more about the progress and outcomes. Please do not hesitate to contact me if I can be of further assistance with this study.

Yours sincerely,

[redacted]

Appendix C: Research & Development department approval letter for 2nd site

NHS

21 September 2015

Claire Browne
Trainee Clinical Psychologist
Lancashire Care NHS Foundation Trust
Division of Health Research, Faculty of Health & Medicine
Furness College
Lancaster University
LANCASTER LA1 4YG

Dear Claire

Study Title	**Adapting Dialectical Behaviour Therapy for clients in a forensic Learning Disability service: What works?**		
REC Reference	**15/NW/0654**	**Trust Project N°**	
Protocol N°	**Thesis Protocol V3 dated 3 July 2015**	**EudraCT No**	**N/a**

This letter provides the formal approval required for your project to commence. Your project is now registered on the R&D database with identification number
It would be helpful if you could use this number on all correspondence with the R & D Office.

Please note that this Trust approval (and your ethics approval) only applies to the current protocol. Any changes to the protocol can only be initiated following further approval from the REC via a protocol amendment; the R&D office should be informed of these changes.

This approval is conditional on members of the research team being substantively employed by the Trust or having appropriate Honorary Research contracts in place before they start data collection. Please contact the R&D office to confirm requirements for any new members of the research team.

In the event that you have applied to have this study adopted to the UKCRN Clinical Research Portfolio, may we take this opportunity to remind you of your responsibility for uploading accrual data for the research site. If you have any difficulty with this process please let us know.

We would like to remind you that as Principal Investigator you are responsible to ensure that the study is conducted within the Research Governance Framework 2005 (RGF) and we encourage you to become fully conversant with the RGF Health and Social Care document. Any breaches of the RGF constitute non-compliance with the RGF and as a result Trust approval may be withdrawn and the project suspended until such issues are resolved.

Please do not hesitate to contact us should you require any additional information or support. May I also take this opportunity to wish you every success with your research.

Yours sincerely

Director of R&D

POSITIVE ABOUT DISABLED PEOPLE
INVESTOR IN PEOPLE

Appendix D: Participant information sheet

Doctorate in Clinical Psychology | Lancaster University

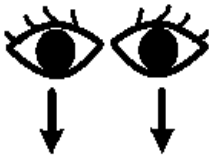
Adapting Dialectical Behaviour Therapy: What works?

Information Sheet

Hello,

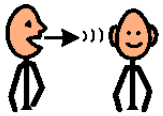
My name is Claire. I am training with Lancaster University to learn how to be a clinical psychologist.

As part of my training I am doing some research.
I would like to know if you want to take part in my research.



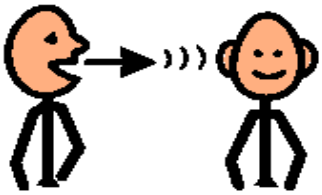
What is the research about?

I have sent you this because you have been to a Dialectical Behaviour Therapy (DBT) group.

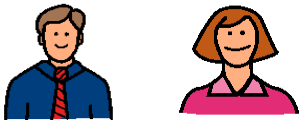


I want to find out what going to the DBT group was like, what helped and what did not help.

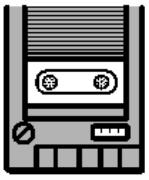
How can I take part in the research?



If you agree to take part, I will come to meet you at (*insert study site*) to talk about the DBT group.



You can ask a staff member to be with you when we talk if you like.



To help me remember what you say, I will record it when we talk. Only me and my supervisor will hear the recording.

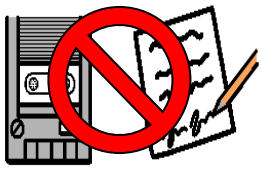
Afterwards, I will listen to the recording and write down what you said.

I hope to publish my research so it can help other people. This means that things you have said will go in reports and publications.

Your real name and other important details will be changed, so that other people will not know that it was you that said things.

Can I say no?

It is ok to say no. This will not change the care you get.



Even if you say yes to taking part, you can change your mind later.

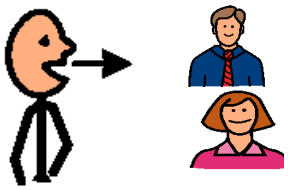
If you tell me you have changed your mind **up to two weeks** after we meet, I will remove your recording and notes from my research. If you tell me **over two weeks** after we met that you do not want to take part, I may struggle to remove your recording and notes but I will try my best.

How will you keep me and my information safe?

The recording will be kept on a password-protected computer. It will be deleted after I have written the research report.

The notes I make will be kept in a locked cabinet for 10 years after the research has ended.

I will tell your Doctor that you are taking part in my study.

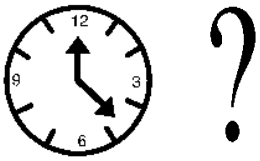


If you tell me that you are going to hurt yourself or someone else, I will have to tell your staff what you said.

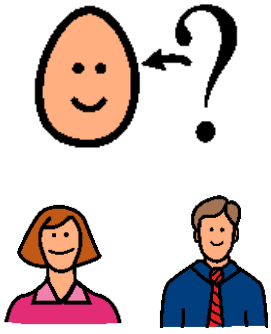
I want to take part. What do I do now?

Please fill in the reply slip, put it in the envelope and give it to a member of staff.

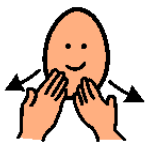
You can ask your key worker to help you fill in the reply slip.



I will ask your key worker to tell me when is the best time to talk to you.



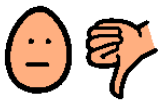
If you have any questions, please tell your Case Manager or key worker. They will tell me your questions so I give you answers.

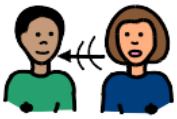


Thank you for thinking about taking part this research.

Claire Browne
Trainee Clinical Psychologist
Lancaster University Doctorate in Clinical Psychology

Complaints:





If you want to make a complaint about this study, tell your Case Manager and they can contact me:

Claire Browne
Trainee Clinical Psychologist, Lancaster University Doctorate in Clinical Psychology
Telephone number: 01524 593 378
Email: c.browne@lancaster.ac.uk

You might not want to tell me your complaint. Complaints can also be made to:

Dr Jane Simpson
Lancaster University Research Director
Telephone number: 01524 592 858
Email: j.simpson2@lancaster.ac.uk
Lancaster University, Lancaster, LA1 4YG

If you want your Case Manager to talk to someone outside of the Lancaster University Doctorate Programme, ask them to contact:

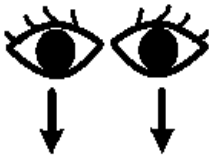
Professor Roger Pickup
Associate Dean for Research
Telephone number: 01524 593 746
Email: r.pickup@lancaster.ac.uk
Faculty of Health and Medicine
Division of Biomedical and Life Sciences
Lancaster University, Lancaster, LA1 4YG

Appendix E: Participant reply slip

Doctorate in Clinical Psychology | Lancaster University

Adapting Dialectical Behaviour Therapy: What works?

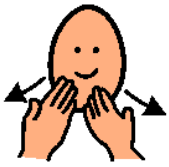
Reply Slip



Please read the 'Information Sheet' – it tells you more about my research.

I do not know your name unless you tell me. Please fill in this reply slip if you might like to take part in the research and want to hear more about it.

You can return this reply slip to me by putting it in the envelope that came with this piece of paper. Give this envelope to a member of staff.



Thank you,
Claire Browne, Trainee Clinical Psychologist,
Lancaster University Doctorate in Clinical Psychology

 **Your name:**
 **Your age:**
  **Your Case Manager's name:**

Appendix F: Letter to MDT regarding participant's capacity to consent to interview

Doctorate in Clinical Psychology | Lancaster University

Claire Browne
Division of Health Research
Faculty of Health & Medicine
Furness Building, Lancaster University
Lancaster, LA1 4YG
Email: c.browne@lancaster.ac.uk
Tel: 07411 532256

Date:

Dear Multi-Disciplinary Team,

I am writing to inform you that _____ has expressed an interest in participating in my thesis research study exploring what aspects of an adapted Dialectical Behaviour Therapy (DBT) skills group are experienced by intellectually disabled forensic service users as helpful for them and why.

This research study is being completed in part-fulfilment of my Doctorate of Clinical Psychology at Lancaster University. I have been granted permission by (service R&D) and ethical approval by the (specific committee) NHS Research Ethics Committee to conduct this research study at (service).

As you will be aware, _____ has attended / is attending an adapted DBT skills group at your service. I have written to _____ providing information about the study (a copy of the correspondence provided is attached) and _____ has returned a reply slip to me indicating his/her interest in taking part in my research.

_____ will be invited to attend an interview conducted at (service) by myself; I am experienced in the assessment and interview of persons with intellectual disabilities and specific communication difficulties. Prior to interview, I shall conduct a brief assessment of _____'s capacity to provide informed consent to participate, and the interview will only go ahead if _____ is deemed able to consent. The length of the interview is flexible and will be dictated by _____'s responses.

If you have any concerns regarding _____'s capacity to provide consent to participate in an interview I would be grateful if you could inform me of such within three weeks of the date of this letter.

If you require any additional information, please contact me via the email address or telephone number provided above.

Yours faithfully,

Claire Browne
Trainee Clinical Psychologist
Lancaster University Doctorate in Clinical Psychology (D.ClinPsy)

Appendix G: Consent protocol

Doctorate in Clinical Psychology | Lancaster University

Capacity Protocol

- Talk through PIS, exploring each point and checking, "What questions do you have?"
- Explain the interview will last as long as they want, they can stop at any time. But that the interview will probably last about 45 minutes.
- Explain they also don't have answer every question I ask; it's ok to say "no".
- Talk through Consent Form – "if you take part, you have to be OK with these things"
- Reiterate voluntary nature / no consequences
- Ask if they think they might want to take part

SAY:

"Thank you (participant's name), I just need to ask a few questions to make sure that I've explained everything properly, is that OK?"

ASK THE FOLLOWING:

1. What will I be talking to you about today?*
2. How long will it take?
3. Can you think of a reason you might not want to talk to me?
4. If you do not want to answer any of my questions, what can you do?*
5. When would I have to tell someone else what you had told me?*
6. Are you still happy to take part in my research?*

*Questions 1, 4 and 5 must be answered correctly.

Questions 2 and 3 can be incorrect, but the interviewer must repeat the correct answer and then check to see the participant has understood by repeating the question.

To be included in the study, question 6 must be answered in the affirmative.

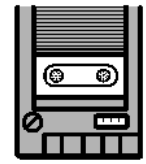
Appendix H: Participant consent form

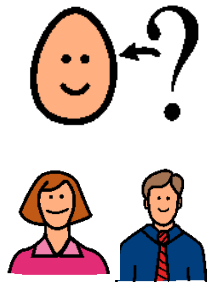
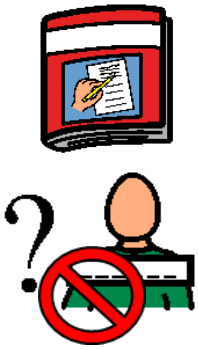
Doctorate in Clinical Psychology | Lancaster University

Adapting Dialectical Behaviour Therapy: What works?

Consent Form to take part in research

Please put your initials in the little boxes on the right if you agree with each statement:

	1. I have read the Participant Information Sheet for this research and I understand what it says. ☐
  	2. I agree to talk to Claire as part of the research. I understand what we say will be audio-recorded and kept on a password-protected computer. It will be typed up and used for the research. I agree that the notes can be kept in a locked filing cabinet for 10 years. ☐
	3. I understand that I can stop talking to Claire at any time. I understand that I can ask for the recording and notes not be used in the study, even after I have talked to Claire. I understand that it might not be possible for my recording and notes to be removed over two weeks after I meet Claire. ☐

	4. I have been able to ask questions about the research. I understand that I can ask more questions at any time by telling my Case Manager. ☐
	5. I agree for Claire to tell my Doctor that I am taking part in this research study. ☐
	6. I agree for things I have said to be in reports. I understand that my real name, birthday and places will be changed so that people do not know it was me who said things. ☐

Please write your name here:

.....

Please sign your name here:

.....

Date:

.....

Researcher name: Claire Browne
Researcher signature:
Date:

Appendix I: Participant debrief sheet

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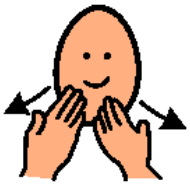
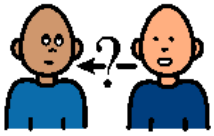
Adapting Dialectical Behaviour Therapy: What works?

If you need support:

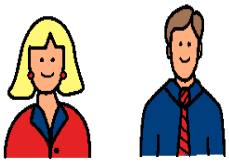


Thank you for taking part in the research.



If you feel upset about anything we have talked about, it is important that you talk to somebody about your feelings.

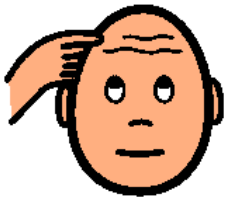
You can talk to a friend or family member you can trust.



You can talk to your Case Manager or keyworker.

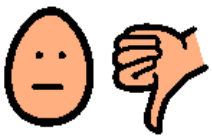
You can talk to your Doctor.

Questions or complaints:



After we have talked, you might want to ask me questions about the research. Tell your Case Manager who will let me know and I will contact you.

My name: Claire Browne (researcher)



If you have any concerns or complaints about this research and you do not want to talk to me, you or your Case Manager can talk to:

Professor Roger Pickup
Lancaster University Associate Dean for Research
Telephone number: 01524 593 746

Appendix J: Initial interview guide

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Interview Structure / Schedule

Research Title: Adapting Dialectical Behaviour Therapy for clients in a forensic learning disability service: A qualitative study of 'what works'.

Introduction to interview: (10-15 minutes*)

The researcher will introduce themselves and discuss the purpose of the study with the participant; revisiting the Participant Information Sheet and answering any questions the participant may have. If the participant states that they wish to continue, the researcher will commence the consent process, considering the participant's capacity to provide consent, discussing in full each point detailed on the Participant Consent Form and again answering any questions the participant may have. Following this, the participant will be asked if they are willing to consent to participate in the study, and if they wish to do so, will be asked to sign the Participant Consent Form and provided with a copy for their own records. Within this discussion, the participant will also be reminded that the interview will be audio recorded, so as to ensure that the researcher can capture all of their responses accurately.

The participant will be reminded that the interview will cover topics that they may find upsetting to talk about. They will be asked how they would like the researcher to respond if they become upset, and reminded of the limits of confidentiality. If the participant appears distressed at any point during of immediately after the interview, the researcher will use their skills developed through training to contain and manage this. The researcher will ensure the participant is aware of how to seek support if they feel this is necessary. Finally, participants will be reminded that they are free to stop the interview at any point if they feel they are becoming distressed, and that they are under no obligation to answer any questions that they feel uncomfortable with.

The participant will then be asked if they would like to provide a pseudonym in place of their real name or the names of anyone they refer to during the course of the interview, or if they would prefer the researcher to allocate pseudonyms.

Interview: (15-60 minutes*)

Following this, the interview will begin. The researcher will switch the audio recorder on and open the recording with the participant pseudonym, date and time, and name of researcher.

The interview schedule below provides examples of the questions that will be asked. This is intended to be used flexibility, with the topic guide evolving in line with the chosen methodology of Grounded Theory and providing opportunity for additional exploratory questions to be asked in response to points raised by the participant.

Conclusion: (5 minutes*)

Following the interview the participant will be thanked for their time and provided with the Debrief Sheet. The researcher will ask the participant if there is anything else they would like to add and whether they feel happy with the interview. The researcher will answer any additional questions that may arise, and reiterate how their data will be used and stored and what will happen with the findings. The participant will be reminded of how to contact the researcher should they have any questions and/or how to seek support following the interview if they experience any distress.

Finally, the researcher will confirm whether the participant would like to receive a summary of the findings after the study is completed.

*(*all timings are approximate, and are to be used as a flexible guideline and in response to the participant's needs.)*

Topic guide:

WHAT CHANGES EXPERIENCED AND HOW THESE CHANGES HAPPENED?

TRY CHRONOLOGICALLY...

- **How did you find out about the group?**
- **What was your first day like?**
- **Can you remember what was talked about?**

- **…(or work backwards…so when was the last time you attended the group?)**

What it was like going to the DBT group?
Example prompts:
- Can you tell me more about that?
- How did that make you feel?
- What did you like?
- What didn't you like?

What was most helpful about the group?
Example prompts:
- Can you tell me more about that?
- Why has that been helpful for you?

What things did you learn that you have been using outside of the group?
Example prompts:
- Can you tell me more about that?
- How has that helped you?
- Can you tell me about a time when you've used that?

Was there anything you found unhelpful about the group?
Example prompts:
- Can you tell me more about that?
- Why was that unhelpful for you?

How could the group have been better?
- What do you think should be changed?
- Was there anything you'd like to have been told?