

**PARTICIPANT OPINIONS OF RANDOMISED CONTROLLED  
TRIALS WITHIN INTELLECTUAL DISABILITY SERVICES**

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I, Daniel John Robotham confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

# ABSTRACT

## **Objective**

This study examined participants' opinions and beliefs about Randomised Controlled Trials (RCTs) in an intellectual disability context.

## **Background**

RCTs in this field require co-operation from various stakeholders, including carers and professionals from a variety of disciplines. However, previous research indicates that local stakeholders may have negative views regarding RCTs in this population, and that it may be difficult for researchers to gain access to participants. This is compounded by the potential problems surrounding communication with a proportion of the service users.

## **Method**

The present study builds upon an RCT for a behaviour therapy intervention for people with intellectual disability, which was situated within community based services in one county of South East England. Fifty-one individuals were interviewed; 11 paid carers, 7 family carers, 6 adults with mild intellectual disability, and 27 professionals from health and social care services. The interviews elicited opinions, beliefs and decision-making processes relating to stakeholder experiences of the RCT. Data was analysed through coding emergent categories into a framework, which evolved throughout the analysis.

## **Results**

The data revealed that opinions about RCTs were shaped by several concerns. The most important of these included the following; continued ability to access interventions, the ethical concerns surrounding randomisation, perceptions of limited financial resources, and problems involving communication and consent.

## **Discussion**

RCTs are ubiquitous in clinical research, including psychiatry. However, they present difficulties for researchers and participants in the field of intellectual disability. Good communication with all stakeholders is essential to ensure the successful conduct of an RCT. This study provides information for academics

and clinicians who plan to conduct future research and RCTs with people who have intellectual disability. The findings may be used in future to develop appropriate strategies to assist with recruitment for RCTs in intellectual disability, and to increase stakeholders' acceptance of the procedure.

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# 1. INTRODUCTION

The field of intellectual disability is often neglected in clinical research. It raises ethical concerns around consent and communication, and these concerns will invariably also relate to the conduct of research. A Randomised Controlled Trial (RCT) is considered to be the most reliable way to test clinical effectiveness. It is the most common scientific research procedure for testing drugs and interventions, and the method has evolved to include pragmatic evaluations in real world scenarios. However, participants in the general population appear to have difficulty in understanding RCTs, so people with intellectual disability may have even greater difficulty. This highlights potential ethical and practical concerns for trials within the intellectual disability field, which underpins the following thesis. Throughout the thesis the terms 'clinical trial' and 'trial' will be used synonymously with RCT.

This chapter is split into two main sections. Section 1.1 describes the background and context to the thesis. The chapter begins by defining key terminology within a cultural and historical context. Section 1.2 comprises the bulk of the chapter. It discusses the public perception of research, specifically with regards to RCTs. A systematic review will aim to illuminate the difficulties of conducting RCTs with people who have intellectual disability whilst simultaneously exploring the perceptions of these trials within this community.

## 1.1 Background and Context

### 1.1.1 Intellectual disability

In the UK, the term 'intellectual disability' is described as *"a significantly reduced ability to understand new or complex information"* and *"a reduced ability to cope independently which started before adulthood, with a lasting effect on development"* (Department of Health, 2001). Internationally, the ICD-10 classification of mental and behavioural disorders describes 'mental retardation' as:

*“a condition of arrested or incomplete development of the mind, which is especially characterized by impairment of skills manifested during the developmental period, which contribute to the overall level of intelligence.”* (World Health Organization, 1992).

The aforementioned definitions show the lack of consistent terminology to describe this client group. The term ‘intellectual disability’ is used in Australia, Canada, and most of Europe. More importantly, its meaning is uniformly consistent across the Western world. The United Kingdom predominately uses the term ‘learning disability’, which is a term that refers to a different client group in the United States. The United States has used ‘mental retardation’ in the past but has recently begun to use ‘developmental disability’. The term ‘intellectual disability’ will be used from here on in order to prevent confusion in terminology.

Regardless of how the term is defined, ‘intellectual disability’ is a complex condition referring to a broad spectrum of individuals. There are typically four gradations of levels of intellectual disability; mild, moderate, severe and profound. Recent Government figures estimate that there are 210,000 people with severe and profound intellectual disability living in the UK, whilst the prevalence rates of mild/moderate intellectual disability has been estimated at 1.2 million (Department of Health, 2001). These figures reflect an administrative prevalence as many individuals, particularly those with mild intellectual disability, are unknown to statutory service providers.

The cause of intellectual disability is often unknown. The most readily identifiable causes are chromosomal abnormalities such as Down’s Syndrome and Fragile X Syndrome. Other common causes are brain injury, complications at birth, and infection during early life. Many people with intellectual disability have additional physical health problems such as epilepsy (McGrother et al, 2006), cerebral palsy or sensory impairments (Centers for Disease Control and Prevention, 2004). Furthermore, there is increasing evidence that people with intellectual disability may develop comorbid mental health problems (Smiley, 2005). Neglect, abandonment by families, bullying, long stays in psychiatric institutions, low self esteem and lack of employment opportunities, as well as

genetic factors have been implicated in the aetiology of increased prevalence rates of mental disorders in this population.

### **1.1.2 The Randomised Controlled Trial**

Within the positivist paradigm, properly designed Randomised Controlled Trials are considered to demonstrate the most reliable form of scientific evidence (Ball et al, 1998). Therefore, RCTs are the 'gold standard' for evaluating the clinical effectiveness of treatments, but their rise to prominence is comparatively recent. The origins of randomisation in clinical trials can be traced back as far as the mid seventeenth century, when Van Helmont suggested a system of drawing lots to decide whether patients suffering from fever should be assigned to a blood-letting treatment (Van Helmont, 1662). Following this, scientists have occasionally used a system of 'alternation' to determine the treatment received by trial patients. For example, the first patient would receive a control substance; the second patient would receive intervention, and so on. Alternation is the true precursor to randomisation in clinical trials, and was used to abolish selection bias and provide more accurate comparisons between different treatments.

The first use of alternation in a large clinical study was by Fibiger (1898) in a trial for serum treatment in patients with diphtheria. Fibiger wanted to ascertain the effectiveness of the serum treatment whilst being able to *"eliminate completely the play of chance and the influence of subjective judgment"*. To achieve this, he split patients into two comparable treatment groups (serum and non-serum). The alternation technique involved treating all patients who came into his hospital on the first day with serum, and those who came in on the second day with a control substance. It is vital to note that this allocation was a deliberate methodological decision on Fibiger's part. He had been unconvinced by the lack of rigour in earlier serum trials (e.g., Roux et al, 1894) and wanted to provide more conclusive evidence for the treatment.

The medical and scientific communities were slow to take heed of Fibiger. Decades later a statistician called Ronald Fisher was the first to relate randomisation to statistical theory (see 'Statistical methods for research workers', 1925; cited by Hróbjartsson et al, 1998). This theory is based upon

the assumption that participants are drawn randomly from a larger population, and that this assumption can be met by randomly assigning participants to experimental groups. Fisher's trial preceded a spate of early attempts at randomisation, for example, Snodgrass & Anderson (1937), Hogarth (1937), and Hopkins (1943). The first fully randomised controlled trial appeared shortly afterwards (Medical Research Council, 1948), aiming to evaluate a Streptomycin treatment for tuberculosis. Participants were allocated treatment or control based upon a system of sealed envelopes which referred back to a statistical series, which had been created prior to treatment allocation.

In the latter study, it is important to note that the statistical series was unknown to the investigators as well as patients. Therefore, investigators as well as participants were unaware of treatment allocation. This is known as a 'double-blind' design, it further ensures that no-one directly connected with the trial can influence the study. This procedure logically extends the 'single-blind' design, in which investigators (but not participants) are made aware of their treatment allocation. Independently of randomisation, the procedure of blinding increases the methodological rigour of a clinical trial. Therefore, a particularly rigorous trial would involve double-blinding as well as random assignment.

From these origins RCTs have evolved and been adapted across a variety of clinical research contexts and settings. Schwartz & Lellouch (1967) were the first to distinguish between 'pragmatic' and 'explanatory' trials in medicine, a distinction that nonetheless runs along a continuum. The influence of their work has grown in time and these distinctions have been revisited more recently by Armitage (1998) and McMahon (2002).

Pragmatic and explanatory trials are distinguished in several ways.

Explanatory trials evaluate the efficacy of a treatment or intervention under controlled, experimental, and 'ideal' conditions. Pragmatic trials evaluate the effectiveness of a treatment or intervention in a real-life context, and necessarily include a heterogeneous population of participants. Explanatory trials measure specific outcomes such as blood pressure or biochemical changes. Pragmatic trials measure wider outcomes, ideally encompassing the full range of health and social benefits from a treatment (Roland & Torgerson, 1998). The

recommendations of a sufficiently rigorous pragmatic trial can theoretically be directly assimilated into clinical practice (Fayers & Hand, 1997). Pragmatic trials are particularly useful for evaluating the effectiveness of 'complex interventions'.

Complex interventions are becoming increasingly common in certain areas of medicine, including psychiatry. There are no clear boundaries between simple and complex interventions. As Craig et al (2008) have described, complex interventions have several interacting components, may involve individuals with complex problems. Some flexibility is afforded whilst tailoring the intervention to individual participants who are likely to have different needs, and there is likely to be increased variability in outcomes. A community treatment for people with severe mental disorders is an example of a complex intervention. The chief concerns for evaluating complex interventions are being able to determine the effectiveness of the model in a real world setting, and understanding how the ingredients of the intervention interact together as a whole.

Pragmatic RCTs with complex interventions are problematic (Hoptoff et al, 1999). Maintaining 'treatment integrity' is difficult; a complex intervention will usually be administered by several healthcare professionals with varying approaches, different levels of skill and experience. In comparison, maintaining treatment integrity in an explanatory drug trial is a routine procedure which comprises measuring, timing and recording of each dose. Complex interventions are often based upon a model but are tailored according to patient needs; the exact details of the intervention may vary from case to case. There is a further issue in finding a relevant comparison arm for the intervention. In practice, pragmatic RCTs usually compare the intervention against the normal care available locally. However, if the local care is substandard or variable in quality, it may not provide an appropriate comparison. An intervention which is ineffective in its own right could be proven effective compared to poor local services. Pragmatic trials may be hindered by the real world scenarios in which they work.

There are specific issues regarding in psychiatry that warrant further discussion compared to those in other medical specialties, and these can affect RCTs.

One of the central principles of randomisation is that participants are recruited upon receiving a particular diagnosis. Mental health depends upon a complex interplay of personal and environmental variables over a period of time. Disorders are less well defined than they are for physical health. A patient's diagnosis may be based on a collection of associated symptoms without an obvious organic cause. Furthermore, there are greater differences in how individuals respond to treatment. All of this makes it difficult to group trial participants into a collective whole (Slade & Priebe, 2001). This somewhat undermines a base assumption of RCTs; that participants' symptoms are similar and the effectiveness of the treatment is ascertained by measuring the effect of the treatment on these symptoms.

Effective treatment of most mental disorders requires both pharmacological and psychotherapeutic methods. The clinical trial framework is less easily adapted for evaluating psychotherapy interventions, where significant differences in a patient's mental health may be detected only after a sufficient time. From the researchers' perspective, such a trial may need to take place over longer time periods to properly evaluate treatment effectiveness (Mulder et al, 2003). This creates an ethical dilemma; how long is it ethical to restrict access to a particular treatment because of trial allocation? For these and other reasons, many widespread psychotherapeutic interventions remain clinically untested, running contrary to the principles of evidence-based practice.

Evidence-based practice (Guyatt, 1992) has been largely responsible for the increasing importance of the RCT as a methodological paradigm. It has two central tenets; any medical innovation should be supported by scientific evidence, and the validity of scientific evidence should be based on methodological rigour. There is a hierarchy of evidence by which studies are judged. A double-blind randomised controlled trial involving a placebo is the second most conclusive form of evidence (after a systematic review of several such trials). A glance at the Cochrane Central Register of Controlled Trials reflects this. The register reveals that the number of RCTs has increased from 2116 listed trials in 1960 to 470,139 in 2006. There is a huge increase in the popularity of the method amongst clinical researchers.

With the number of RCTs expanding, guidelines were put in place to ensure quality standards for such trials. There are complex ethical considerations behind randomised controlled trials. Two main concerns are evident from Fibiger's trial (Fibiger, 1898). First, some participants are inevitably allocated to a control group. Second, patients were not asked for their consent before taking part. Increased methodological rigour raises greater concern for human rights. Trials were often conducted without patients' consent in the past (Wald et al, 1995). Before examining the specific ethical issues regarding RCTs it is necessary to demonstrate how research ethics have become inseparable from the research process.

### **1.1.3 Research Ethics**

Concern for the ethical issues surrounding research owes a great deal to the Nazi experiments during World War II. The infamous experiments conducted by Nazi doctors at concentration camps have been well documented. For example, prisoners at Dachau were thrown into freezing water to test how long a pilot could survive if they were shot down over the sea. The Nuremberg Code (1947) was drawn up following the conviction of sixteen Nazi doctors for crimes against humanity. This code includes the principles of informed consent, the right to withdraw, and the need for research to benefit society. It also argues against the coercion of research participants. This code provides the basis for most subsequent medical research ethics frameworks. These principles paved the way for increasingly rigorous guidelines in the years to come.

The World Medical Association Declaration of Helsinki was adopted in 1964 (amended – 1975, 1983, 1989, 1996, 2000, 2002, 2004, 2008). This aims to legally enforce the issue of informed consent. The emphasis is on the voluntary nature of research participation. Theoretically, no-one should enlist in any research without making an informed choice. In practice, scientific journals will refuse to publish articles of research involving human subjects when they fail to adhere to these rules. The declaration also states that informed consent should be obtained in writing. Each participant should be:

*“adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the*

*anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal".*

Research proposals in the UK are reviewed by a Research Ethics Committee. This is an independent body which seeks to maintain ethical standards in research. The committee may question any ethical issue arising from a research proposal in the UK. Institutions that regularly fund clinical research in the UK also have ethical frameworks. The Medical Research Council (2005), the Wellcome Trust (2005) and the Royal College of Psychiatrists (RCPsych, 2004) all have guidelines that should be adhered to by researchers who undertake the process of research. These guidelines cover similar ground, in that research should be conducted responsibly, ensure participant confidentiality, balance benefit against risk, contribute to scientific understanding, and ultimately improve public health and well-being.

Historically, people with intellectual disability have had an uneasy relationship with research ethics. The controversial Willowbrook State School experiments (1963 – 1966; see Rothman & Rothman, 1984) and the human radiation experiments (1944 – 1974; see Advisory Committee on Human Radiation Experiments, 1996) are high-profile examples of unethical research with this population. Research in the field of intellectual disability therefore requires meticulous planning, and any intervention for use with this population needs to be carefully designed.

Various issues have been debated in the academic literature regarding the ethical problems of conducting research with people with intellectual disability. These include providing informed consent (Fisher et al, 2006; Evenhuis et al, 2004; Iacono & Murray, 2003; Freedman, 2001; Weisstub & Arboleda-Florez, 1997; Fox et al, 1983), advocating by proxy (Evenhuis et al, 2004; Yan & Munir, 2004; Rosenstein & Miller, 2003; Freedman, 2001; Weisstub & Arboleda-Florez, 1997), the possible conflict of interests of research aims between society and individual (Liddell, 2006; Scott et al, 2006), the need to balance the risks and benefits of becoming a research participant (Liddell, 2006; Kellett et al, 2004;



Yan & Munir, 2004; Freedman, 2001; Arscott et al, 1998; Gordon & Miller, 1981), and the unequal power balance that may exist between researcher and a participant with intellectual disability (Bollard, 2003; Freedman, 2001; Brodin & Renbald, 2000; Swain et al, 1998). Research involving participants with learning disability is made more difficult because of these ethical considerations.

Previous literature suggests that people with intellectual disability may have difficulty in understanding complex concepts. A person with intellectual disability is likely to have a smaller vocabulary (Burnip, 2002), and may find it difficult to form sentences. Tasks that people with intellectual disability may find challenging include understanding perceptions of time (Janeslätt et al, 2008), abstraction (Carrasmunda et al, 2006), understanding question words such as 'who?', 'how?' or 'why?' (Morgan et al, 2009), and engaging with central executive processes in working memory (Van der Molen et al, 2007). Many of these functions are employed by participants who are asked to take part in a research project, especially if the project involves complicated methodology and several repeat follow-up appointments over a period of time. Therefore, these deficits are likely to cause problems for people with intellectual disability who are asked to make a decision about whether to participate in research, based on their understanding of the research activity and the implications of participating or not.

#### **1.1.4 The Mental Capacity Act**

Many published articles describe how codes of practice can relate to research in incapacitated participants such as people with intellectual disability (Liddell, 2006; Yan & Munir 2004; Freedman, 2001; Morris & Hoschouer, 1980). The published literature covers a wide range of debate regarding the related concept of 'best interest' (Ashcroft et al 2001; Freedman, 2001). The standard of best interest is now legally enshrined within the Mental Capacity Act 2005 for England and Wales, in the United Kingdom (Department for Constitutional Affairs & Department of Health, 2005). It is based upon the principle that taking part in a particular research study will be in the best interest of the research participant (Iacono & Murray, 2003).

The Mental Capacity Act 2005 for England and Wales received Royal Assent in 2005 and was implemented in April 2007. This act encompasses research ethics as well as other areas such as contract law and healthcare. Among other things, it aims to protect people who lack capacity to make certain decisions about participation in clinical research. The most common examples of populations who may lack mental capacity consent are as follows; those with Alzheimer's syndrome, those with severe mental illness, patients in comatose state, people with intellectual disability. Section 1 of the Act outlines five main principles:

*“- A person must be assumed to have capacity unless it is established that he lacks capacity.*

*- A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success.*

*- A person is not to be treated as unable to make a decision merely because he makes an unwise decision.*

*- An act done, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests.*

*- Before the act is done, or the decision is made, regard must be had to whether the purpose for which it is needed can be as effectively achieved in a way that is less restrictive of the person's rights and freedom of action.”*

Prior to the Mental Capacity Act (2005), research involving people who lacked decisional capacity involved carer assent. This use of assent began in the UK in the late 1990's with participants who lacked the ability to provide consent. The Mental Capacity Act states that non-professional carers or nominated third parties need to be contacted to give full 'consent' on behalf of the person without decisional capacity. The difference between assent and consent is subtle for the purpose of research; the Act has essentially provided an official guideline for a grey area. Assent can be defined as making a decision on someone else's behalf; consent can be defined as taking responsibility for a decision made on someone else's behalf.

It remains to be seen how the Mental Capacity Act (2005) will affect research in situations where the potential research participant lacks the capacity to consent. It is possible that much needed research will be impeded or abandoned due to assumptions about people who cannot provide informed consent. It is nevertheless apparent that research involving mentally incapacitated participants, including people with intellectual disability will need to involve co-operation with third-parties. This increases the onus on effective and honest communication with participants about the aims, potential benefits and risks with regard to research. This would better equip them to make a more informed decision based upon their appraisal of the ethical issues.

### **1.1.5 Equipoise in Randomised Controlled Trials**

The main concern about the ethics of RCTs is that some participants are inevitably randomised to a comparison group instead of receiving a new treatment. The concept of equipoise has been influential as an ethical justification and scientific rationale behind random allocation in clinical trials (Gifford, 2007). A clinical community adopts a position of clinical equipoise when there is uncertainty about whether one treatment is more effective than another. The state of equipoise arises because there is insubstantial evidence to suggest that one treatment is superior. In other words, a methodologically rigorous RCT is needed to provide solid evidence. Theoretically it is ethical to randomly allocate treatment in a state of genuine clinical equipoise; one treatment could be just as effective as another and no-one therefore receives preferential treatment.

Clinical equipoise is also referred to as 'collective equipoise' to distinguish it from 'personal equipoise'. The latter refers to an *individual* clinician's opinion regarding the relative effectiveness of two or more alternative treatments. A clinician should maintain personal equipoise if he/she strictly obeys the code of evidence-based medicine. Clinicians should distance themselves from the situation and disregard their preferences for certain unproven treatments; not an easy position to achieve (Young et al, 2004). Alderson (1996) argues that any clinician who has not accepted a position of personal equipoise is obliged to adopt the general position of clinical equipoise. A rationale for this is that lack of personal equipoise may be indicative of a clinician's ignorance of available

evidence, or on their own personal preference. Edwards et al (1998) report that only a quarter of clinicians thought they could achieve personal equipoise.

The voluntary involvement of patients (participants) in a randomised trial assumes that the general public is able to understand equipoise. Evidence suggests that this is not necessarily the case (Mills et al, 2003). Firstly, they may be unwilling to accept that clinicians could have no treatment preferences. Secondly, they may have treatment preferences themselves, usually for a new treatment over an old one (Chalmers, 1997). Thirdly, treatment preferences are dynamic; they may change if treatment has no noticeable effect during the trial (Snowden et al, 1997), and participants may hear reports of new treatments from outside sources. The general public and the clinical community approach equipoise from different perspectives, but both appear to have difficulty accepting it. The second part of this chapter will begin to illuminate this in greater detail.

## **1.2 Participant Experiences**

The arguments surrounding equipoise in the academic literature undoubtedly reflect the need to take participant views and experiences into account when conducting research. The second part of this chapter will focus on participant experiences with research and RCTs. Participant opinions will be appraised through their comprehension of certain key aspects of randomisation. These ideas form the backbone of the thesis, so a systematic review will be presented. The review investigates the scientific literature regarding the ethical and practical problems of conducting randomised controlled trials in the field of intellectual disability.

### **1.2.1 Researcher / participant relationships**

Clinical research should ultimately benefit the public, and it is important for researchers to maintain good relations with the public. These relations can be improved by understanding how the public comprehends clinical research. The fundamentals of clinical research are well known to the scientific community, but they are not common knowledge. There are disparities in the way researchers

and the general public view research. Clinical research almost always requires public involvement and so the implications are clear - it is important to understand how and why these disparities exist. Researchers who understand how the general public views their work will optimise the benefits of their research.

Researchers and the general public regard research differently. Field & Powell (2001) suggest that researchers view research as an ongoing process generating questions and raising disputes, which is difficult to present in terms of output and definitive answers. They claim that the public need to understand how scientific disputes help to shape the formation of knowledge. Bauminster (1981) suggests that research only impacts on policy when it has moved from the realm of 'scientific' knowledge into the realm of 'ordinary' knowledge. Bridging between the two is not a straightforward task; fundamental differences in approach create a gulf between science and the general public. It is sensible to consider how the two sides can learn from each other. Traditional science keeps an objective distance from its subject, so researchers are privy to the mechanics of research but not to the direct concerns of the public in context. In contrast, participants have firsthand knowledge of their problems and of local clinical services, but are unlikely to have a formal understanding of research mechanics. Clinical research can benefit everyone, but the full benefits will not be felt unless researchers and the general public understand one another.

The importance of these relationships is arguably magnified in pragmatic RCTs. This paradigm represents an intrusive type of research that can alter the patterns of service delivery and treatment in a local area. It is important for researchers to take account of the context in which they work (Victor et al, 2004). The cultural and environmental characteristics of the area are an integral part of a pragmatic research trial. This may be further complicated within the field of intellectual disability. Professionals and carers working alongside people with intellectual disability can themselves become trial participants, although they may not be research 'subjects' in the traditional sense (Jackson, 1999). The list of people who 'participate' in a pragmatic RCT for people with intellectual disability is extensive. Care-staff, care-home

managers, health professionals, psychiatric services, social workers, support workers, service users and their families could all qualify.

The network will have varying familiarity with research methodology; they will have differing interests and varying levels of influence. The Mental Capacity Act (2005) specifies that many of these third-parties will need to be called upon to influence the consent process, and their opinions and comprehension of the research will affect the trial. The remainder of this chapter reviews two areas of the literature. First, it discusses participant opinions and comprehension of RCTs within the general population. Secondly, it presents a more specific systematic review of the practical and ethical problems relating to RCTs involving people with intellectual disability.

### **1.2.2 Opinions about Randomised Controlled Trials**

There is a moderate base of literature relating to lay comprehension of randomised controlled trials. In the UK, two reports have reviewed relevant studies (Robinson et al, 2004; Edwards et al, 1998). Some studies have included real trial participants (Heaven et al 2005; Snowden et al, 1997). Others have used hypothetical scenarios to study what the general public thinks and understands about RCTs (Bjorn et al, 1999; Davis et al, 1998). Two surveys have examined the comprehension of RCT participants with intellectual disability (Fisher et al, 2006; Arscott et al, 1998). However, no body of theory has yet been developed from these investigations (Robinson et al, 2004).

Most research in this area has focused on the potential for increasing recruitment. In clinical research, researchers have addressed the following questions while investigating participant views:

- What motivates people to participate in randomised trials?
- Do participants fully understand the concept of randomisation?
- How satisfied are participants with their experience of randomised trials?
- How do participant treatment preferences affect trial integrity?
- Are trials conducted with sufficient regard for informed consent?

In a review paper of participant perspectives and RCT ethics, Edwards et al (1998) found that the most commonly cited factors for RCT participation were altruism and self-interest. Of the two, self-interest was more frequently cited than altruism. Participants who cite altruism are motivated by the idea of helping others who suffer from a similar condition. The finding for self-interest is more difficult to interpret because at first sight it would seem that participants have nothing to gain directly from taking part. There is a number of ways in which participants could benefit indirectly. They could be attracted to the idea of receiving extra medical attention by taking part. A survey study by Gerard et al (1995) noted that patients with more severe symptoms were more likely to agree to participate in a trial. They may join to gain information and increase their awareness with regard to their particular condition, or they may gain access to social networks which they would not otherwise have found. Trial participation could be seen as a self-empowering, knowledge-seeking, social exercise for those participants who cite 'self-interest'.

There is mounting evidence to suggest that the findings for self-interest are due to participants' comprehension of the RCT. Edwards et al (1998) in their review were concerned by the number of participants who claimed to be motivated by self-interest, stating that in a climate of clinical equipoise, participants will not gain or lose anything from participating. They argue that participants need to formally understand the principles of equipoise and randomisation before agreeing to take part. Participants need to be aware of any potential risks. It is likely that people are misinformed because they fail to appreciate the principle of equipoise and the reasoning behind random allocation. Some participants believe that trials can be conducted equally effectively without randomisation (Robinson et al, 2004). This misinformation affects the potential participant's ability to make an informed choice before consenting to take part. The implications of misunderstanding question the notion of informed consent and relate back to the principles in the Declaration of Helsinki (2008).

The evidence of participant misunderstanding shall now be presented in detail. Robinson et al (2004) have created a framework which appraises how participants comprehend RCT situations, and many of the framework's

elements are incorporated into Figure 1. This is a diagrammatic representation of a model which tracks the decision-making process of an individual participant.

**Figure 1** – Participants' decision making processes in an RCT

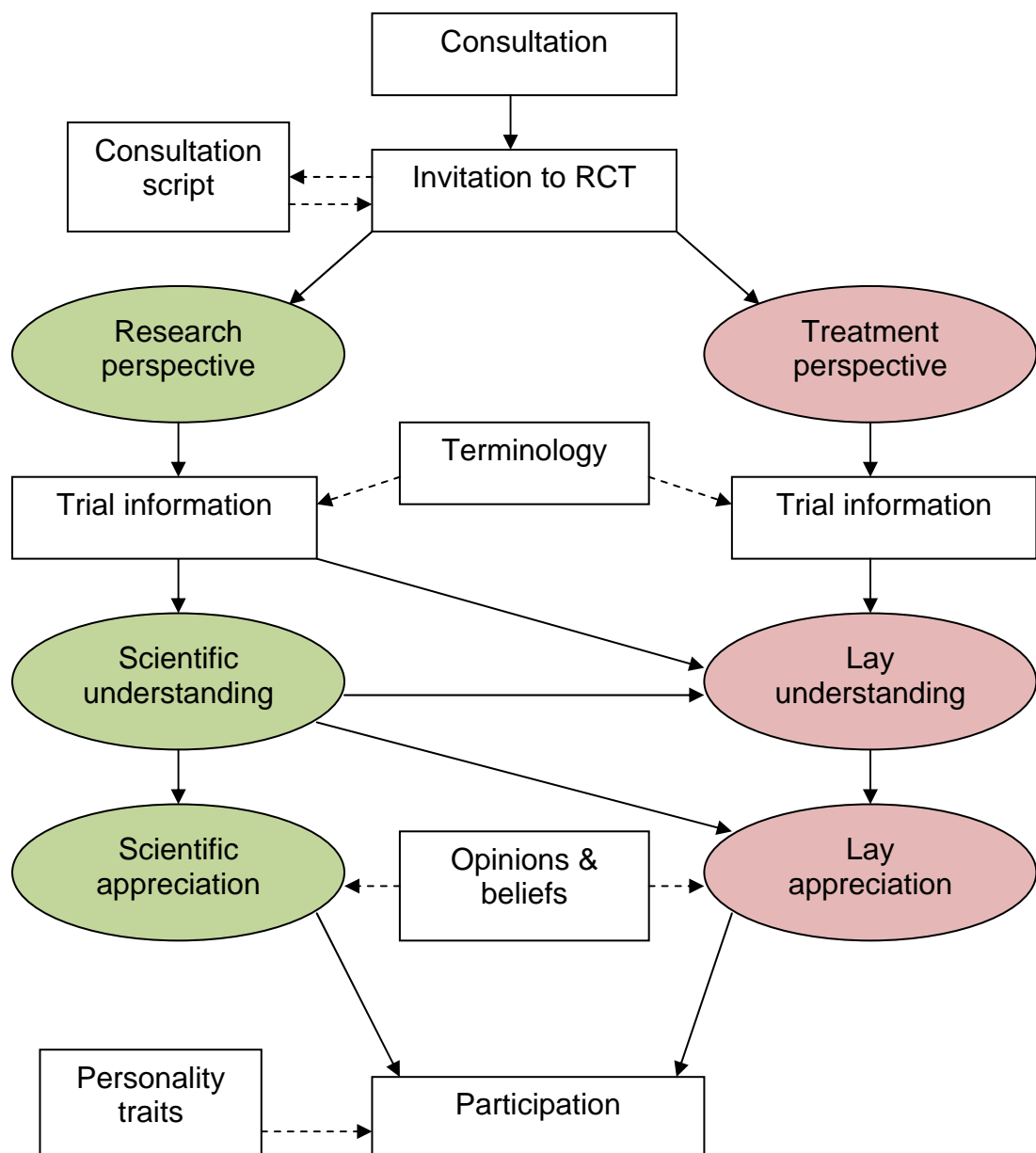


Figure 1 relates to the lay person's view upon being invited to participate in a trial. This is centered on how people understand and interpret the world and has roots in social science ideas such as script theory. According to Schank & Abelson (1977), people relate to the world by referring to prior specific knowledge about situations. This specific knowledge is grouped together into 'scripts'; a patient who visits the doctor will refer to a 'consultation script' to help



interpret the events of the consultation in context. An example script for a doctor/patient consultation may resemble the following scenario, as shown in Figure 2.

**Figure 2** – Typical consultation script

David feels unwell – Appraises symptoms – Decides to visit doctor – Enters waiting room – Speaks to receptionist – Sits in waiting room – Receptionist calls his name – Goes through to consulting room – Talks to doctor about concerns – Doctor asks about symptoms – Doctor examines David – Doctor suggests treatment – Doctor prescribes treatment – David takes prescription – Doctor tells David to come back if he continues to have problems – David leaves
--

A sequence such as this will be relevant to the large majority of consultations between patients and GPs. This script has been constructed upon David's previous encounters with his GP. It will also depend upon David's beliefs about the roles of GPs within society, such as the idea that his GP is there to look after his health, and that the GP will act in his best interests. Spence (1960) has described this process as:

*“the essential unit of medical practice is the occasion when, in the intimacy of the consulting room, a person who is ill, or believes himself to be ill, seeks the advice of a doctor whom he trusts. This is a consultation, and all else in medicine derives from it”*

Incidentally, the script may differ if David was speaking to a nurse at a hospital about his symptoms, because David would invoke the 'hospital script' and the 'nurse script'. However, there would be broad similarities between the two – David is still consulting with a health professional about a problem, so there would be considerable overlap between the scripts.

Invitations to clinical research trials may arise during a clinical consultation about a patient's particular ailment. However, the invitation to participate is not part of the standard consultation script between health professional and patient. For this reason it is unlikely that this event will fit into a patient's standard consultation script. Figure 3 shows this alternative script, with the changes to the script highlighted.

### **Figure 3** – Atypical consultation script

David feels unwell – Appraises symptoms – Decides to visit doctor – Enters waiting room – Speaks to receptionist – Sits in waiting room – Receptionist calls his name – Goes through to consulting room – Talks to doctor about concerns – Doctor asks about symptoms – Doctor examines David – **Doctor tells David that a new drug might help him – Doctor explains that this treatment is only available as part of a trial – Doctor invites David to take part in a trial.**

The idea of consultation scripts will now be related back to model in Figure 1. The standard consultation script is altered when the health professional invites the patient to take part in a trial. A patient is expected to notice this change in the consultation script as an ‘unexpected turn’ of events (Robinson et al, 2004). The patient may fail to recognise this unexpected turn and continues to appraise the consultation from their standard script (a ‘treatment perspective’). Providing any further information about study method is unlikely to enhance the scientific understanding of someone who is viewing the situation from the standard script. These individuals thus may form a ‘therapeutic misconception’ regarding the aims of the trial. This term was originally coined by Appelbaum et al (1987), and has received significant attention in published literature (Appelbaum & Lidz, 2006). Henderson et al (2007) define it thus:

*“Therapeutic misconception exists when individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study or from other aspects of the clinical trial.”*

Henderson et al (2007) suggest five domains that participants should understand in order to avoid therapeutic misconceptions; purpose, procedure, uncertainty, clinician relationship, protocol adherence. This is likely to occur when a participant believes that a health professional is certain about the efficacy of the treatment, and will act in the participant’s best interests. Patients with a therapeutic misconception will not have a scientific understanding of the process throughout the course of the trial, including the consent procedure.

On the other hand, some patients will recognise the invitation to participate in a clinical trial as an ‘unexpected turn’ in their usual doctor/patient interaction.

They will make the shift from the standard consultation script into the 'research context'. They will use the information to appraise the reasons behind the use of randomisation in the trial. Participants who do not fully understand the process are likely to resort back to their own lay interpretations to make sense of it. These lay interpretations are sometimes known as 'folk theories', for example, random allocation is seen as a way of limiting access to treatments when resources are scarce (Featherstone & Donovan, 2002). Patients who have not conceptualised the aims, methods and rationale of a trial in a scientific way are liable to revert to lay interpretations, because lay interpretations relate to more widely shared beliefs. Robinson et al (2004) suggest that this is influential when participants attempt to make sense of RCTs.

Attempting to replace lay understanding with scientific understanding is difficult. This is because the two can co-exist even when they contradict each other (Windschitl, 2004). Robinson et al (2004) suggest that people resort to lay understandings because they are applicable in a broader context. For example, an information sheet explaining the rationale for RCT method is only relevant in this narrow context. On the other hand, the belief that a doctor will provide the necessary care in accordance with the patient's situation is more widely held. A scientific understanding may form initially, but this may be demoted later in favour of an understanding relating to a person's lay interpretation.

Featherstone & Donovan (1998) argue that the terminology used in clinical trials is liable to confuse people. Confusion of terminology could cause participants to form a lay understanding. The authors argue that the phrase 'randomised controlled trial' itself is unclear; the primary dictionary definition of 'random' refers to something with "*no specific pattern, purpose, or objective*". This is quite different to the secondary definition of the word, "*of or relating to an event in which all outcomes are equally likely*" (Dictionary.com, 2006). It is the secondary definition which is applicable in the context of a randomised controlled trial. Similar confusion may arise from words such as 'trial', which may be seen as 'trying something out', the word 'research', which could be understood as 'research into someone's problem', and the word 'controlled' may be understood as 'secure' or 'careful'. The researcher and the participant

approach the situation from a different perspective, the language they use may serve to set up a barrier between them.

A therapeutic misconception will arise if participants draw upon lay understandings. Heaven et al (2005) take the 'therapeutic misconception' a step further. They explored 'trial identity' using observational data from RCT participants. The authors revealed a spectrum of participant beliefs regarding their role within a trial. Participants with a scientific understanding viewed themselves as 'medical volunteers'. Participants with lay understanding viewed themselves as 'patients'. The study suggests that the former group reported greater feelings of satisfaction and less disappointment with the trial. These findings indicate that participants will benefit more if they understand their contribution within a research context. The alternative explanation is that the former group participated via conscious choice, whereas some participants of the latter group may have consented passively under a therapeutic misconception.

Participants may understand the methodological issues of a trial, such as the possibility of joining a control group and the random allocation. This alone may not prevent them from reverting to a lay understanding. A participant will be less likely to continue to understand the trial in a scientific context if they do not relate the methodological concepts to the research itself. The distinction between understanding and appreciation was made by Lidz et al (2004); a participant with scientific understanding appreciates the methodological benefits of randomisation for clinical trials. Such participants have formed a similar conception of the trial to the researchers themselves. These participants can make a choice about participation which is based upon a scientific understanding of the trial and the specifics of the method. The interplay between scientific and lay interpretations is likely to be complex and dynamic, and the concepts of equipoise and random allocation may be alienating.

Previous research in this area is disjointed, and there is no collective theoretical framework. Snowden et al (1997) highlight the importance of scientific understanding. Their study sought the opinions of parents enlisted in a trial of a life-support intervention for newborn infants. Some participants were angry that

random allocation had denied them a potentially life-saving opportunity for their child, others viewed randomisation as a barrier to accessing their preferred treatment, and still others held a therapeutic misconception that the clinician would attempt everything possible to help save the child. A minority fully understood the methodological rationale of the trial, but would trade off the possible negative effects of an unproven intervention against the possible benefits. Clinicians were unable to offer the new treatment to participants in the control group until the end of the trial because it would jeopardise the quality of the trial. A study such as this shows that many participants understand research situations in lay terms, making decisions they may later regret.

This study also emphasises the benefits of scientific over lay understanding by trial participants, which should be seen in conjunction with the requirements of informed consent described in the Declaration of Helsinki (2008). In relation to the aforementioned script theory, lay understandings appear to have broader applicability to participant lives than scientific understandings. Participants understand situations in a way that appears to make most sense to their daily lives. However, in RCTs and other types of clinical research, it is the researcher who sets the conditions of trial procedure. Many people may involve themselves in clinical trials under the belief that it is in their best interests. These connotations reach across the whole spectrum of clinical research, but it is time to re-introduce the problems inherent in intellectual disability research. The literature regarding research in intellectual disability has been systematically reviewed and is presented below.

### **1.2.3 Participant attitudes of RCTs within intellectual disability**

The systematic review focuses on how researchers and participants in the field of intellectual disability have reflected on their experiences of research. Information from the review has been published (Robotham & Hassiotis, 2009) and is attached in Appendix 7.2. The purpose is to examine issues and barriers to conducting RCTs in the field of intellectual disability. This information will be appraised from the perspective of relevant research stakeholders; participants, families, carers, local service providers and researchers themselves. A systematic review of the literature was conducted. Six computerised bibliographical databases were searched (PubMed, EmBASE, Dissertation

Abstracts, Web of Science – SCI expanded and SSCI, PsychInfo and CENTRAL). The references of key papers found during the review were hand-searched. A search equation was built from search terms. Details of the search are available in Appendix 7.3. The references retrieved were matched against the following inclusion and exclusion criteria:

1. Focus:

The focus was ‘intellectual disability’ defined in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) as ‘mental retardation, characterized *“by significantly sub average intellectual functioning (an IQ of approximately 69 or below) with onset before age 18 years and concurrent deficits or impairments in adaptive functioning”* (American Psychiatric Association, 1994).

2. Participants:

Articles were included if participants were adults and/or children with intellectual disability. Articles involving infants with intellectual disability were excluded, since this research almost exclusively focuses on genetic and biological aspects of the disability. These are outside the scope of this review.

3. Approach:

Papers of two types were included; articles where researchers reflected on prior experience with RCTs (opinion driven), and studies seeking participant opinions on RCTs (investigative).

4. Time of publication:

In the last forty years there have been great changes in attitudes towards people with intellectual disability. Anything written before that time would be far removed from the concerns of interested parties within the current research framework in intellectual disability. Anything published prior to 1966 was excluded.

A data extraction form was used to retrieve relevant information from each paper. For investigative studies this included aims, method and key findings. For opinion driven articles included aims and significant points of interest. The

investigative articles were appraised according to methodological strength, relevance of focus, depth, and clarity. However, there are no standardised tools for appraising opinion driven literature. Three appraisal criteria were devised. These were based upon the aims of this specific review to distinguish between the relative usefulness of the included articles. Reflectivity was the most important criterion; the extent to which researchers were reflecting on their own first-hand experiences of conducting RCTs in the field. Papers were excluded if they were not based on experiences in the field. Articles were then judged on secondary criteria of clarity and logicity. Clarity referred to readability and clarity of aims and conclusions. Logicity referred to the extent to which the article logically presented the information in relation to the authors' own experience.

A total of 12,369 unique records were retrieved. One reviewer, myself, scanned the title (and if relevant, abstract) of each record, 155 records were deemed relevant for further investigation. Each abstract was reviewed by me and my PhD supervisor (AH), in order to determine whether to obtain the full-text. Each was reviewed independently and then discussed. Any reference deemed relevant by either researcher was included. Any reference deemed irrelevant by both researchers was excluded. A total of 77 references were short-listed and obtained. Another eight references were found by hand-searching cited references in the papers. Therefore, 85 articles were considered for the review. The authors reached consensus that nine studies met the inclusion criteria; five quantitative investigative articles and four opinion driven articles. Table 1 summarises these articles.

**Table 1** – Summary of included articles

Author	Year	Country	Journal title	Type of paper
Tierney et al	2007	USA	Psychopharmacology	Investigative
Fisher et al	2006	USA	American Journal of Psychiatry	Investigative
Lennox et al	2005	Australia	Journal of Intellectual Disabilities Research	Opinion driven
Martin et al	2005	UK	Journal of Intellectual Disabilities Research	Opinion driven
Vitiello et al	2005	USA	Journal of the American Academy of Child and Adolescent Psychiatry	Investigative
Drew et al	2002	UK	European Child and Adolescent Psychiatry	Opinion driven
McAdam et al	2002	USA	American Journal of Mental Retardation	Investigative
Oliver et al	2002	UK	Journal of Intellectual Disabilities Research	Opinion driven
Aman & Wolford	1995	USA	Journal of the American Academy of Child and Adolescent Psychiatry	Investigative

*i. Investigative articles:*

Fisher et al (2006) explored how well participants with intellectual disability understand RCT concepts. The sample (n=150) included equal numbers of people with mild intellectual disability, moderate intellectual disability, and of average intelligence. People with mental illness were excluded, and functional intelligence was measured at the outset using the Kaufman Brief Intelligence Test. The Assessment of Consent Capacity – Randomized Clinical Trials (ACC-RCT) was used in conjunction with a vignette to elicit open-ended responses. The vignette described a hypothetical drug trial for aggressive behaviours. Participant responses to the vignette were converted into quantitative data to measure participant understanding. Surprisingly, the results indicated that people with mild intellectual disability had a good understanding of the nature and purpose of research, and most were able to make choices about participation. Randomisation and placebos were the most difficult concepts to understand, especially by people with moderate intellectual disability.



Two studies have aimed to examine satisfaction of carers of participants with intellectual disability regarding drug RCTs. Aman & Wolford (1995) and McAdam et al (2002) both asked primary caregivers to complete a seven-item study satisfaction questionnaire. The former study involved using methylphenidate and fenfluramine in children with intellectual disability and attention-deficit hyperactivity disorder. The latter study investigated the effects of risperidone on behaviour for people with intellectual disability. In the former study, participants were mailed questionnaires four weeks after completion of the RCT; the latter study was similar though the time period is not reported. Both studies found high levels of satisfaction amongst participants. McAdam et al (2002) reported that all respondents (n=17) were satisfied and 82% would enrol in a similar study again. Aman & Wolford (1995) reported 83% satisfaction, with 88% claiming that they would be happy to enrol again (n=40).

Two further publications emerged from a Risperidone vs. placebo RCT for behaviour problems in children (aged 5-17) with autism and intellectual disability (Tierney et al, 2007; Vitiello et al, 2005). In both studies the parents/guardians were followed up with questionnaires after the RCT was completed. The results of Tierney et al (2007) mirror those of Aman & Wolford (1995) and McAdam et al (2002). They used a questionnaire including eight Likert scale questions and two open-ended questions. They obtained a sufficiently high response rate of 95% (n=96). Up to 96% of the participants were satisfied with their experience in the trial. An even greater proportion of participants (99%) said they would choose to do it again in future, and would recommend the trial to other parents.

Vitiello et al (2005) approached the same group of RCT participants (n=95) with a different focus. Their aim was to highlight how well parents of children with autism understood RCT concepts. The authors asked participants who had been involved in a real trial scenario. The After Study Knowledge questionnaire is a 13-item multiple-choice questionnaire designed to test a participant's knowledge of concepts such as study purpose, understanding, right to withdraw, side effects, placebo control, and randomisation. Participants had a good understanding of consent (99%) but a much less good understanding of randomisation (72%). Table 2 provides a methodological overview of each of the five investigative articles.

**Table 2** – Summary of investigative articles

Study	Hypothetical/real	Method	Participants	Survey Response rate
Tierney et al, 2007	Real RCT participants	Quantitative survey	96 primary carers	95%
Fisher et al, 2006	Hypothetical RCT examples	Quantitative comparison	50 people with mild ID 50 people with moderate ID 50 people with no ID	N/A
Vitiello et al, 2005	Real RCT participants	Quantitative survey	95 primary carers	95%
McAdam et al, 2002	Real RCT participants	Quantitative survey	17 primary carers	81%
Aman & Wolford, 1995	Real RCT participants	Quantitative survey	40 primary carers	64%

\*ID = Intellectual disability

### ii. Opinion-driven articles

The opinion driven articles all reflected upon issues that had occurred when conducting RCTs with people who had intellectual disability. Table 3 summarises the main features of the four opinion driven articles:

**Table 3** – Summary of opinion driven articles

Study	Sample	Focus	Method (of study described)
Lennox et al (2005)	Adults with ID, carers	Comparison of two health improvement interventions	RCT
Martin et al (2005)	Adults with ID, carers	Assertive community treatment vs. standard treatment	RCT – pilot study for multi-centre trial
Drew et al (2002)	Children with autism, ID, carers	Parent-training intervention vs. standard treatment	RCT
Oliver et al (2002)	Adults with ID, carers	Assertive community treatment vs. standard treatment	RCT

Three papers (Lennox et al 2005; Martin et al 2005; Oliver et al, 2002) offer detailed reflective accounts of research issues in pragmatic RCTs in intellectual disability. Drew et al (2002) have reflected over a RCT for an intervention in children with autism. Several themes arise from these articles:

## 1. Consent

Lennox et al (2005) and Oliver et al (2002) describe consent as a barrier and an ethical problem. Lennox et al (2005) highlight the issues surrounding proxy advocacy, finding that only 11% of their 216 participants were able to consent fully. Proxy advocates did not always have close relationships with clients, and in some cases consent problems were reinforced by carer illiteracy. The procedure may be complicated by hierarchies of consent required for individuals living within large-scale care organisations.

## 2. Access

'Gate-keeping' refers to third party individuals and organisations blocking researchers' access to participants. Lennox et al (2005) emphasise the need for the researcher to understand local service terminology and to be accepted by the community who are involved with people who have intellectual disability. However, this does not preclude future difficulties in the recruitment of participants. This relates to the idea of making local contacts within care organisations, and the hierarchy of influence means that the researcher should develop relationships with senior professionals as well as keyworkers. Oliver et al (2002) highlight the importance of successful collaboration between researchers and local health professionals in order to improve accessibility. However, individuals with mild intellectual disability may still be difficult to seek because they may live in temporary accommodation or be unknown to services.

## 3. Resources

The perceived lack of resources within the community is a problem both for researchers and participants (Lennox et al, 2005; Oliver et al, 2002). Research was seen as a drain on resources, particularly for overburdened care staff, and 40% of potential research sites in the Oliver et al (2002) study withdrew for resource reasons. Drew et al (2002) and Martin et al (2005) argue from the researchers' perspective. The former voices concern over the limits of research funding in implementing an intervention. Martin et al (2005) worry that limited service resources may compromise treatment integrity in RCTs; the culture of overlapping staff duties within services could mean that staff delivering an intervention may also end up delivering the treatment for people in the control group. This represents a general problem of all pragmatic RCTs.

#### 4. Treatment integrity

Pragmatic RCTs of complex interventions (Martin et al, 2005; Drew et al, 2002; Oliver et al, 2002) show the importance of maintaining 'treatment integrity'. The outcomes for standard treatment and intervention can only be accurately compared if they are internally consistent. A negative trial result may arise if the intervention and control group are too similar (e.g. Martin et al, 2005), or because of inconsistencies in how the control or intervention is delivered across geographical areas (Oliver et al, 2002). An intervention that is based upon training other people (such as Drew et al, 2002) ultimately relies on the quality of the training and the diligence and ability of those being trained.

#### 5. Measuring outcomes

Oliver et al (2002) note the difficulties of measuring outcomes of treatment and intervention in intellectual disability RCTs. Clinical differences due to treatment within this population are often slight, and occur over a long period of time. Therefore, this creates problems in detecting subtle clinical differences, and suggests a need for long-term follow up periods to detect them. Further, there are problems associated with relying on proxy measurements; Drew et al (2002) doubted the accuracy of outcome measurements that were based upon parental report.

#### 6. Ethics

Martin et al (2005) and Oliver et al (2002) note that participants may have preferences for one treatment over another, such as a reluctance to accept the control treatment for the trial period. Many participants and stakeholders from participating services were concerned about the ethics of randomisation. This relates to RCTs in all populations, not just within intellectual disability.

#### *iii. Appraisal of studies*

The articles discussed previously indicate that there are significant impediments in RCTs in intellectual disability from the perspective of the researchers and the participants. Any RCT with this population requires co-operation with carers and local services. The quantitative studies suggest that participants and carers have a reasonably accurate understanding of the demands of RCT participation and report that they are satisfied with their participation, although

there is evidence that they may fail to understand the randomisation process. The opinion driven articles show the extent of co-operation required for an effective RCT, which may include residential care organisations and back up from health workers. Also evident is that these services are expected to 'gate-keep' for individuals with intellectual disability, so the consent procedure invariably involves a number of stakeholders. The perceived lack of resources appears to affect the willingness of services to co-operate and the potential for researchers to achieve accurate outcomes.

The articles presented in this review are appraised for their relative applicability and usefulness in revealing the issues relating to RCTs. All five investigative studies use quantitative methodology, allowing comparisons to be made between them. However, they do not illuminate participants' opinions and understandings in depth. In contrast, the opinion driven articles do provide rich contextual information but fail to investigate participants' or carers' views. The studies complement each other but there is a knowledge gap to be filled; research participation is a complex phenomenon, and mixed methods research would likely be a better approach for exploring these problems.

Of the three studies that measured participant satisfaction of an RCT, both McAdam et al (2002) and Aman & Wolford (1995) are limited by small sample sizes. Tierney et al (2007) present a stronger study with more methodological detail and a larger sample size. All three studies are hindered because the trial investigators administered the satisfaction questionnaires. This fact may have influenced participant responses and may partially account for the high participant satisfaction rates found. Furthermore, none of the questionnaires appear to have been piloted, and their psychometric properties are unknown.

Two studies investigated how individuals understood RCTs. Fisher et al (2006) asked participants to respond to a hypothetical situation based upon a familiar scenario; a drug trial for challenging behaviours in people with intellectual disability. Vitiello et al (2005) used real trial participants. Fisher et al (2006) describe how participants could remember and repeat the information given on a hypothetical vignette, but that they may not fully understand the principles of participation in RCTs. This presents a problem in the light of prior research, for

example, Appelbaum et al (1987) argued that participants without intellectual disability develop a dual understanding of trial mechanics and rationale; a dominant 'lay understanding' alongside a 'scientific understanding'. As already discussed, this conflict is described as the 'therapeutic misconception'. Vitiello et al (2005) pay attention to the therapeutic misconception in their study because only 72% of their participants understood that treatment was administered via randomisation. They see this as a potential area for future research but it is not addressed by the study design.

Lennox et al (2005) and Oliver et al (2002) are the most comprehensive opinion driven articles. Both deal exclusively with research issues and both come to similar conclusions. Incidentally, it should be noted that Lennox et al (2005) conducted a qualitative feedback exercise during the baseline assessment of the RCT they were conducting. They asked participants questions about problems encountered with enrolling, and questions regarding participant expectations about the RCT. Participants revealed few problems with enrolling, but 36% of participants described self-interested motives for participating in comparison to altruistic motives (26%). However, these findings cannot be critically appraised accurately because the authors present minimal information about their method and results. The articles by Martin et al (2005) and Drew et al (2002) primarily function to describe the method and outcomes of an RCT. Therefore, discussion of research issues within these two articles is limited and largely anecdotal.

#### **1.2.4 Intellectual disability RCTs**

The systematic review has provided detailed information about the problems of conducting RCTs in the intellectual disability field. It suggests some ways in which the process might be made easier. The review highlights the need to establish rapport between the clinical research and the community of service users, carers and professionals who are involved with intellectual disability. By extension, it shows how this kind of research in intellectual disability creates large interacting networks of local stakeholders, who may influence the trial, which may be similar to trials with many other groups of participants. The issues of research participation need to be viewed in the light of people's perceptions and opinions about a trial. How are opinions formed? How do

participants comprehend the trial? How can they influence it? The information from the review will now be assimilated into the aforementioned model of participant comprehension shown earlier (Figure 1).

Many of the barriers to participation could stem from a lack of prior experience with clinical research. Intellectual disability is a field that straddles a number of organisational boundaries; mental health and social services, specialist and general health care. These services are delivered within a complex care framework of people who could influence a clinical trial. This research context presents a complex challenge for researchers. Health and social care staff working with people who have intellectual disability may never have encountered clinical research, creating a vicious circle. People without prior experience of research are more likely to resort to lay comprehensions about it, rather than scientific ones. This in turn may fuel the climate of suspicion around randomised controlled trials. The success of pragmatic RCTs depends upon how well they fit into the surroundings. The onus lies with the researchers to investigate the context. Figure 4 presents a modified version of the conceptual diagram presented in Figure 1. This version of the model has been adapted in relation to the findings of the systematic review.

**Figure 4** – Participants' decision making processes in an RCT for people with intellectual disability

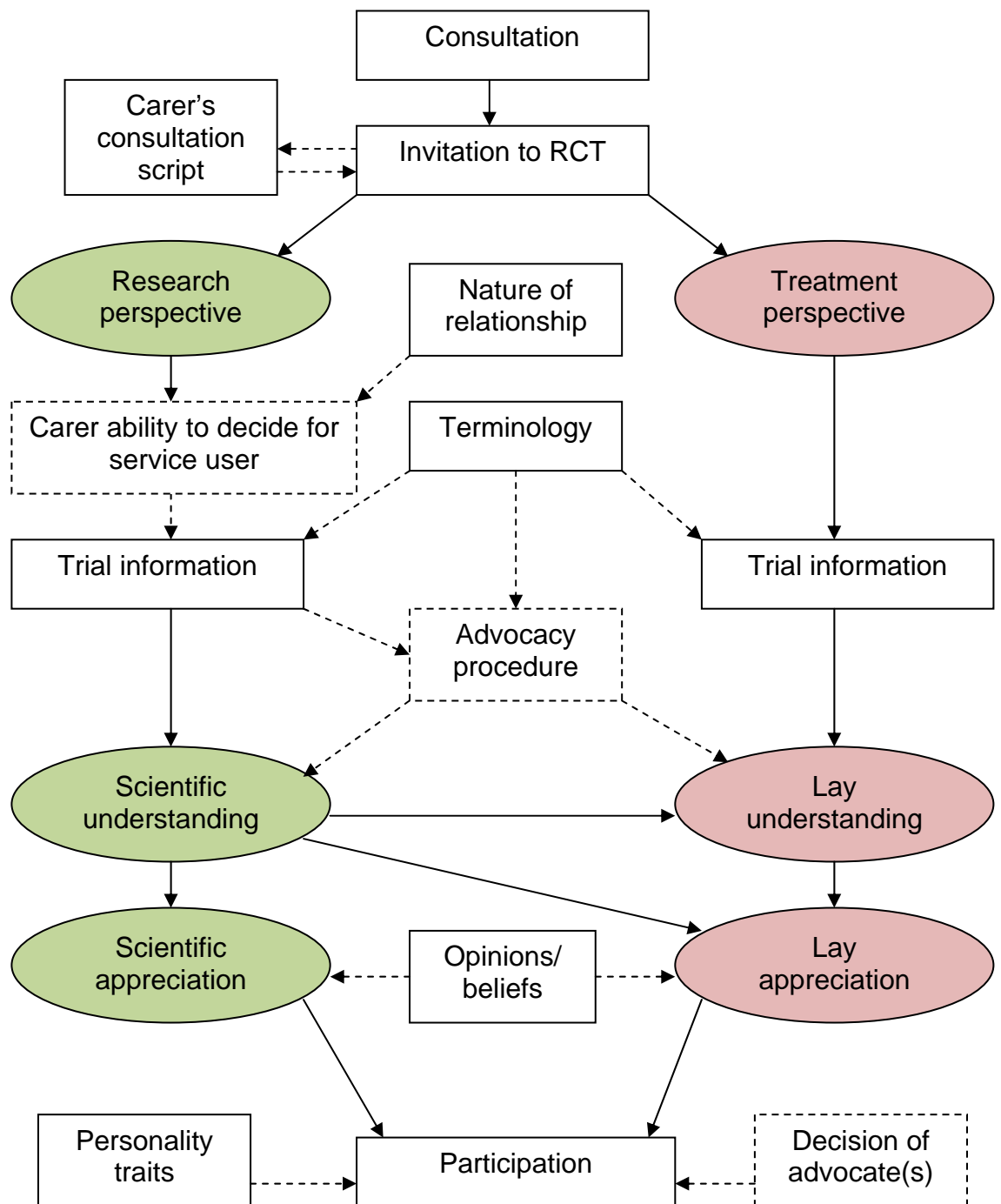


Figure 4 attempts to conceptualise the context of an RCT in the field of intellectual disability, by adding specific elements not included in Figure 1. To date, no-one has investigated this context in relation to participant opinions and comprehension. It is true that every different RCT will have a unique context, but it is likely that there will be overarching themes that are applicable to any clinical research in this field. Figure 4 accounts for the fact that there will be multiple people who can wield an influence. The service user is not the only



participant with a conception of the trial. Decisions about trial participation may be outsourced to professional carers, family members or independent advocates. This process is likely to occur in most cases when the service user lacks any capacity to ever make this kind of decision.

Figure 4 involves a more complicated and intricate network of stakeholders than Figure 1. It indicates the potential for barriers as highlighted by Lennox et al (2005) and Oliver et al (2002). A carer who feels uncomfortable with the idea of making a decision on behalf of the service user will be unlikely to sign up for the trial on the spot. He or she may refuse to consent, or may wish to consult other people first as part of the advocacy procedure. The information about the trial is disseminated and it may require a multi-disciplinary meeting amongst health and social care professionals who are involved with the service user's care.

The opinions of other stakeholders have not been as well researched as those of patient participants. Edwards et al (1998) reviewed the literature involving the wider population, and much of it refers to the opinions of clinicians regarding the ethics of randomisation and equipoise. There is very little work on how people in this position conceptualise the research process for RCTs. Still, it is important to avoid assuming that these people form a scientific understanding of the process simply because they work in a clinical setting.

It is important to note that this Figure 4 only accounts for situations where the onus of decision making is passed from service user to carer. The characteristics of intellectual disability have already been discussed, but it is important to re-iterate that the severity of intellectual disability is on a continuum. Many service users are capable of making their own decision without the help of a carer. This is particularly likely in cases where the service user is defined as having 'borderline intelligence'. In other cases, the carer may be present only as a supportive influence, and the ultimate responsibility and decision lies with the service user. People in this situation are likely to fit into the original model presented in Figure 1, although there are possible differences; the perceived gulf in power between the health professional and the client is greater than in the general population (Swain et al, 1998), and it has been shown that people

with intellectual disability are more suggestible and compliant than those without intellectual disability (Gudjonsson & Henry, 2003).

The following paragraphs discuss the implications of the conceptual model described in Figure 4 on the perceptions of various types of stakeholders in the RCT process. In a pragmatic RCT in intellectual disability, the permission of service users, family carers, paid carers and professionals may be required.

*Service users:*

As discussed, people with intellectual disability may have cognitive limitations and difficulty interpreting abstract concepts. Therefore it would be reasonable to assume that they may have some difficulty understanding the rationale and procedure that underpin an RCT. It may be argued that, ultimately, the research is aimed to benefit the lives of this population and that therefore the person with intellectual disability has the largest stake of all in the research. It may affect their future treatment and care. It is also important to consider how the level of intellectual disability is likely to affect a person's understanding. An individual with mild intellectual disability is likely to understand research procedures better than a person with severe or profound intellectual disability.

*Family carers:*

It is estimated that half of the people with intellectual disability in the UK are living with their parents and a further 12% with other relatives (Emerson et al, 2005). This creates a large number of family carers. These carers are likely to have daily interaction with one particular individual who has an intellectual disability. They therefore will know the service user well and have a good understanding of their needs. In some cases the family carers may be the stakeholders who initiate the process of enlisting in an RCT, based on their own attempts to seek help from professionals. Their views and wishes may or may not be congruent with those of the participant, but they may often be accustomed to speaking on behalf of a less able family member. Family carers are unlikely to have more than a lay understanding of research prior to taking part in an RCT, unless they have had previous co-incidental experience with research such as a university degree, or previous experience of taking part in similar research. Personal attitudes regarding the treatment of people with

intellectual disability will be important; these may be seen within the context of historical accounts of abusive practices with people with intellectual disability in institutions, or in research.

*Paid carers:*

Just under a third of people with intellectual disability in the UK are living in some form of supported accommodation (Emerson et al, 2005), and will receive paid care. Paid carers may form strong bonds with service users. They are likely to work in teams to support service users, but primary responsibility for one particular service user often rests with one key-worker. They may work in a variety of settings, such as a day centre or a residential care home, and they may move from one home to another in a relatively short space of time. Some may be peripatetic, visiting service users on a regular basis to provide home support. Their understanding of research and RCTs is likely to depend upon their educational or clinical background (for instance, only a minority of residential carers are qualified nurses), and they may have misconceptions about RCTs. Paid carers may often not feel able or qualified to make research decisions on behalf of a service user who cannot provide informed consent. In these instances, they will often involve family members, senior staff or professionals in helping to make the decision. They may also have developed views about professional services based upon numerous prior experiences of providing care for several service users.

*Professionals:*

This group of stakeholders is often consulted when problems arise with an individual service user. In this context, the vast majority of professionals come from two broad backgrounds; health and social care, although they often work in multi-disciplinary teams that cross these boundaries. This stakeholder group includes qualified people from a number of accredited professions such as medicine, nursing, psychology, or social work. This group may also include support staff working within these teams, such as community support workers.

Professionals are likely to have less contact with service users individually than carers, although they may have contact with a wider range of service users and carers than any of the other stakeholder groups. Professionals may be asked

for advice from carers regarding research studies, they may also be asked to recruit participants themselves. Clinicians may be enthusiastic to assist recruitment in RCTs, but recruitment could still be difficult because of conflict with clinical duties or perceived lack of expertise about how to recruit participants to trials (Oliver-Africano et al, 2009). Professionals therefore act as important gate-keepers for researchers who wish to access people with intellectual disability.

Importantly, a pragmatic RCT alters the role of a health or social care professional. In normal clinical practice, the professional is expected to appraise the options and do what is best in order to help each individual client. This situation is more complicated when the clinician and patient are co-operating with an RCT, since certain interventions will instead be offered through a system of randomised allocation. Professionals' understanding of RCTs is likely to relate to their education and training, many may be familiar with research (particularly clinical and nursing staff), and others may not.

### **1.2.5 Aims and Objectives**

The study to be described in this thesis builds on previous limited research investigating participant experiences with RCTs. Previous studies as referred to in this chapter have largely reflected upon the views of carers. The following study investigates the opinions of a wider network of stakeholders, within the context of a pragmatic RCT of a service for adults with intellectual disability. Stakeholder experiences will be investigated in accordance with the following research questions:

- In what context do RCTs in the intellectual disability field operate?
- What is the level of understanding of trial participants for an RCT in the intellectual disability field?
- To what extent do service users, carers and professionals accept the fundamental aspects of randomisation?

### **1.3 Summary**

Few RCTs have been attempted in the field of intellectual disability, and many of these cases have met with a range of practical difficulties, including objections from stakeholders. Little is known about how stakeholders in the intellectual disability community (i.e., service users, carers and professionals) experience RCTs. Therapeutic misconception and lay understanding of RCTs are common in other clinical populations, which has raised implications about the ethics of informed consent. This may cause further complications in intellectual disability RCTs, due to increasing numbers of potential stakeholders and limitations in the service users' capacity and cognitive communication abilities. Because of these problems, researchers may avoid conducting research in this area. Intellectual disability services will continue to lag behind mainstream mental health services in terms of enhancing effectiveness in service user care. Prior theoretical research from other clinical populations is used to guide the initial assumptions of this study, which will attempt to investigate stakeholder experiences within an RCT in the field of intellectual disability. The following chapter will describe the method that was used to answer the aforementioned research questions.

## **2. METHOD**

This chapter is split into three sections; context, data collection and data management. This chapter begins by outlining a context for the population and area that has been studied. The idea for the present study was conceived whilst working as a researcher on an RCT. The RCT examined an intervention for people with intellectual disability who had been referred to specialist support services funded by the NHS. An overview of the local area context and information about the local service structure will be presented in Section 2.1. Section 2.2 describes the data collection processes, with regard to the sampling, method and procedure. Qualitative interview data comprised the bulk of the study, but some quantitative data was also collected. Section 2.3 focuses on the process of data management, including data analysis. Special attention is paid to how the analytical process evolved. The problems of rigour and credibility in qualitative analyses are discussed in relation to the scientific paradigm in which they operate. Where possible, this chapter will refer to the study in the traditional third-person, but I will also use the first-person to highlight the choices made whilst conducting the study.

### **2.1 Context**

#### **2.1.1 Essex demographics**

Essex is a large county in the East of England. It covers a total population of 1,645,900 (Office for National Statistics, 2005). The Census (Office for National Statistics, 2001) provides more detailed information; the population is slightly older than the national average; there are a greater proportion of people in the age category “45 and over”. The county also has a much lower proportion of people from non-white ethnic backgrounds (2.9%), than the average across England of 9%. Essex has similar distributions across socio-economic class as the rest of England, although the unemployment rate was less than the national average (3.6% compared to 5%). The administrative headquarters of the county are based in Chelmsford. The other principal towns in Essex are Colchester and Southend-on-Sea.

### **2.1.2 South Essex NHS Trust Organisation**

South Essex Partnership University NHS Foundation Trust (SEPT) is a mental health trust that serves a population of around 715,000 within five sectors (Brentwood, Basildon, Rochford & Castle Point, Southend and Thurrock). The trust employs approximately 2000 staff members and has an annual budget of around £100 million. The Trust has secondary mental health services for adults, older people, children and young people, and people with intellectual disability. The intellectual disability service caters for people aged 16 and above. The service treats individuals with mental illness, autism, challenging behaviour, epilepsy, and degenerating neurological disorders within this population. The service provision comprises one community learning disability team for each of the five sectors, short-stay and long-stay inpatient units, an occupational therapy service, a speech and language therapy service, and a tertiary behaviour therapy service for people who display challenging behaviour.

The history of the current Trust has been complicated by the number of mergers that have occurred in recent years. Southend Community Care Trust merged with Thameside Community Care Trust in 2000, which later changed its name to South Essex Mental Health and Community Care Trust. This in turn became South Essex Partnership NHS Trust in 2004. In May 2006 it changed again to become South Essex Partnership NHS Foundation Trust. A Foundation Trust differs from a regular NHS Trust because they are run locally and have a certain degree of autonomy from the Government. The Department of Health (2008) provides the following definition:

*“NHS Foundation Trusts are a new type of NHS organisation, established as independent, not for profit public benefit corporations with accountability to their local communities rather than Central Government control. The Secretary of State for Health has no powers of direction over them. NHS Foundation Trusts remain firmly part of the NHS and exist to provide and develop healthcare services for NHS patients in a way that is consistent with NHS standards and principles.”*

The five community learning disability teams are multi-disciplinary and comprise of staff from both the Foundation Trust and social services. The staff group

consists of consultant psychiatrists, community mental health nurses, social workers, occupational therapists, speech and language therapists, psychologists, community support workers and administrative staff. The nursing staff within each team is headed by a Healthcare Co-ordinator (a H-grade mental health nurse). The social care workers within each team are headed by a senior social worker team manager and are managed within social services rather than by the Foundation Trust.

The Trust has since become South Essex Partnership University NHS Foundation Trust. Prior to this, it had established links with two universities in Essex. Anglia Ruskin University (ARU) is co-located in Essex and Cambridgeshire and it has a campus in Chelmsford. The University of Essex is based in Colchester and Southend. The Trust employs a professor of mental health as a Chairperson for research activity. In addition, the Trust employs a Research Manager and up to seven clinical staff who spend one day per week in research activity. Throughout 2006 there were 12 research projects underway, eight of these were externally funded and four were without external funding. The Trust reported an annual total outlay of £24,872 on research and development. This is a relatively small amount if compared with the neighbouring North Essex Mental Health Partnership NHS Trust, who reported an outlay of £96,926 (Department of Health, 2006).

### **2.1.3 The Behaviour Therapy Team**

The Behaviour Therapy Team is a specialist tertiary service for people with intellectual disability who display 'challenging behaviour'. Emerson (1995) defined challenging behaviour as:

*“culturally abnormal behaviour(s) of such intensity, frequency or duration that the physical safety of the person or others is likely to be placed in serious jeopardy, or behaviour which is likely to seriously limit use of, or result in the person being denied access to, ordinary community facilities.”*

This definition includes a variety of behaviours such as aggression, self injury, stereotyped behaviours, and hyperactivity. All of these may also occur in the



context of comorbid mental illness. Challenging behaviour is common amongst people with intellectual disability, prevalence rates range from 3% to almost 36% (Hassiotis & Hall, 2008).

The behaviour therapy service is predominantly based upon the ideas of the Institute of Applied Behaviour Analysis (IABA). The IABA has developed since the early 1980s and their model is a widely used non-pharmacological intervention for challenging behaviour. (LaVigna & Willis, 2005; 1995). The model comprises proactive and reactive behavioural strategies. Proactive strategies aim to promote long-term changes in behaviour by empowering the client. Reactive strategies aim to deal with problem behaviours as they occur.

The proactive elements of the model are positive programming, focused support and environmental changes. Positive programming teaches general skills which will allow the client to integrate more fully into their environment. Focused support strategies concentrate on particular areas where the client may be experiencing problems. Environmental changes may also be made to the client's home and surroundings. The variety of elements in the model attempts to tackle challenging behaviour across many time-scales. Carers should continue employing these strategies after the Behaviour Therapy Team has completed working with the client. The team have recently begun to apply a Cognitive Behavioural Therapy model for clients who have mental health problems and sufficient communication skills.

The Behaviour Therapy Team was started in 1994 under Southend Community Care Trust (NHS). The team initially consisted of two people, it steadily grew and at the time of writing there were ten members of staff (nine full-time members, one part-time member). There were four fully qualified staff, two staff with diplomas, and four support workers. In 2002, one of the original members of the team was employed as a Nurse Consultant in Challenging Behaviour. This person was based on site with the Behaviour Therapy Team but was no longer part of the team itself. Half of the work for this post involved seeing clients; the other half was related to the service development for the local NHS Trust. In 2003, two full-time members of the Behaviour Therapy Team set up an adjunct intervention for mental health problems. This was based upon

Cognitive Behavioural Therapy. These two staff members were embedded within the larger team. In 2004 the Behaviour Therapy Team was merged with other behaviour services within the Trust. The behaviour specialist nurse who covered the Basildon and Brentwood areas was integrated into the team.

Referrals to the Behaviour Therapy Team were made through the local community intellectual disability teams. The most common referral patterns were through the community nurse, social worker or psychiatrists. A member of the Behaviour Therapy Team then made contact with each referral and informed them about the possibility of participating in an RCT.

#### **2.1.4 Randomised Evaluation of a Behaviour Intervention in Learning Disabilities (REBILD)**

Behavioural models such as the IABA could be a useful way of treating challenging behaviour among people with intellectual disability. At the present time however, there is limited evidence of clinical effectiveness for such interventions. Whitaker (1993) warns against mistaking theoretical soundness for robust evidence. A Cochrane Review of four small randomised controlled trials of behavioural and cognitive behavioural interventions showed that the evidence for behavioural interventions is inconclusive (Hassiotis & Hall, 2008).

The Randomised Evaluation of a Behaviour Intervention for Learning Disabilities (REBILD) aimed to evaluate the clinical and cost effectiveness of an intervention for people with intellectual disability and challenging behaviour. Two experimental groups were compared; (1) the standard service available locally, (2) specialist service given by the Behaviour Therapy Team. The trial recruited 63 participants over a period of two years between September 2005 and June 2007. The sample consisted of all adults with intellectual disability who had been referred for challenging behaviour and were drawn from the five sectors of South Essex Partnership University NHS Foundation Trust. Two of the five sectors, Southend and Rochford have had access to the Behaviour Therapy Team for several years. Prior to the beginning of the trial the input of the Behaviour Therapy Team was extended to cover the other three sectors. The findings from the REBILD trial are presented in Hassiotis et al (2009; see Appendix 7.1 for the published abstract).

Participants were randomly allocated to one of two trial arms, either the Behaviour Therapy Team, or standard treatment control group, who received treatment as usual as provided by the community intellectual disability teams. Randomisation was conducted on an individual basis using sealed allocations. The complex clinical nature of the intervention made it impossible to blind participants to the experimental group into which they had been allocated. However, the field researcher, I, was blind to the randomisation process and participant treatment allocation. The participants were followed up over a period of six-months. During this time the participants remained within their treatment groups. At the end of the trial, participants who were randomised to the control group were invited to access the Behaviour Therapy Team if they still required.

The process for gaining informed consent from the participants was complicated and multi-faceted. The Behaviour Therapy Team first assessed the referral and passed on information about the trial. If the person agreed to be contacted, I made contact with each potential participant as soon as possible after receiving the details. I explained the purpose of the research and the principle of randomisation over the phone. People with intellectual disability were not usually the primary contacts at this stage. The contact was most often a keyworker at a residential home or a parent, occasionally it was a staff member at local day services. I made appointments to meet each service user along with their carer. I explained the procedure of the trial to participants again and provided them with written information sheets for them to keep. Written consent was gained following this process. Information sheets followed the guidelines produced by Consumers for Ethics in Research (1994). Information for people with intellectual disability was similar but used simpler language and pictures (i.e., accessible format). These information sheets were reviewed by a Speech and Language department within two different Trusts, including SEPT. Health professionals were briefed about the REBILD trial and regular updates were published in local Trust newsletters.

### **2.1.5 Behavioural Advisory Team**

It is necessary to provide a brief outline of the work of the Behaviour Advisory Team, who was unknown to the researchers prior to the beginning of the trial.

This team provides similar input to the Behaviour Therapy Team, working with people who have challenging behaviour and intellectual disability. The team was funded by Essex County Council, so it was a social services team rather than a health team. However, this fact is important to consider because of the integration of health and social care within the learning disability services, and the fact that referrals were made to the Behaviour Advisory Team through the local community learning disability teams. Geographically it covered several areas in Essex including Brentwood and Basildon – which were also served by the Behaviour Therapy Team. The Behaviour Advisory Team consisted of three behavioural advisors and two support workers working alongside service users and carers within residential placements. Their work took place primarily with clients who were undergoing the transition phase between child/adolescent services to adult services. In a small number of cases, this team may have been used as an alternative for those professionals who were unable to access the Behaviour Therapy Team for participants who were taking part in REBILD.

#### **2.1.6 The researcher's role**

Within the constructivist paradigm, the researcher is assumed to exert influence on the context of a qualitative study. Results are assumed to arise from the relationship between the researcher and the researched. Therefore, the researcher is required to reveal any important demographic facts, along with their own stance and position.

I am a white male, 28 years of age at the time of writing. I have an undergraduate degree in psychology and a postgraduate degree in health psychology. I also have experience of working in the field of mental health. I have previously conducted research interviews with elderly people in nursing homes and people with diabetes. I had been working with people who have intellectual disability and challenging behaviour for three years, conducting research interviews with service users and their direct care staff. I was solely responsible for collecting participant data in the REBILD study and I was also responsible for the day-to-day management of the project. In many ways I was the public face of the REBILD trial for people in the local area, since I was the member of the team who was most frequently seen at local team meetings within the Trust. During my time in the post I had been working alongside

health professionals from South Essex Partnership University NHS Foundation Trust, which included members of the Behaviour Therapy Team and the other local health and social care services.

## **2.2 Data Collection**

### **2.2.1 Sampling and Recruitment**

Participants for the present qualitative study were drawn from the five sectors of the South Essex Partnership University NHS Foundation Trust (Basildon, Brentwood, Rochford, Southend and Thurrock). Participants can be subdivided by type into the following categories:

- A) Service users with mild intellectual disability and challenging behaviour. Participants were able to partake in conversation and were able to give informed consent without the help of a third-party (n=6).
- B) Family carers of service users who have intellectual disability and challenging behaviour (n=7).
- C) Paid carers of service users who have intellectual disability and challenging behaviour (n=11).
- D) Health and social care professionals who work with people who have intellectual disability. Participants were drawn from intellectual disability services within the local area (n=27).

Participants included those who had participated in the RCT within intellectual disability services; service users and carers. It also included people who had been less directly involved, such as professionals from the local services.

Sampling from groups A, B and C was drawn from a pool of individuals who had participated in the REBILD trial. In order to avoid unblinding myself to the participants' trial arm, each participant was recruited following their completion of participation in the RCT. Participants were given information about the study, and were asked to sign a consent form in order to participate in the interview. Simplified pictorial information sheets and consent forms were given to service users where appropriate, and these are available in Appendix 7.5. Carers were

interviewed if they joined the study after October 2005, and the earliest trial participants were not interviewed. This was because the present study was conceived whilst the RCT was already taking place.

A problem with sampling people with intellectual disability for the present study was that many did not have the capacity to participate, or were unable to give informed consent. Participation in a qualitative interview required abstract thought and the ability to answer questions posed by myself, the interviewer. Challenging behaviour, the primary inclusion criteria for REBILD, is proportionally more common amongst people with more severe intellectual disability. Hence, half of the participants in REBILD were deemed unable to participate in a qualitative interview.

Furthermore, the majority of service users from the RCT had moderate to severe intellectual disability (50 out of 63). Where possible, an official diagnosis of the severity of intellectual disability was gained by examining clinical notes or each REBILD participant. However, some service users enlisted into the RCT had never received prior clinical input. In these cases, gradation of the severity of intellectual disability was based upon conversations with parents and other stakeholders (such as social workers). Furthermore, I used personal judgment of each service user's capacity to take part in the qualitative interview. This was based upon the three previous meetings I had had with them during the data collection phase of the RCT.

In practice, these sampling techniques meant that only service users with mild intellectual disability and good communication skills were included in this present study. Accordingly, thirteen service users who had participated in the RCT were judged to have mild intellectual disability. Of these, two were suffering from poorly controlled schizophrenia and were judged to be incapable of participating in a qualitative interview. Two service users refused to take part in a qualitative interview, and a further three had moved into alternative accommodation and were difficult to contact. This left a potential pool of seven participants, of which six were interviewed.

Sampling from group D; health and social care professionals, was purposive to achieve maximum variation for the different professions within the multi-disciplinary teams. I obtained a copy of the health and social services register for staff working in the intellectual disability services. All these staff had worked within the catchment areas of South Essex during the time in which REBILD had taken place. I also included several members of the Behaviour Therapy Team itself. I aimed to recruit a sample of professionals that was representative of service composition; for instance, there were many more community nurses and social workers than speech & language therapists and psychologists working within the region. Therefore, the majority of the professional sample comprised of community nurses and social workers. The sample varied on how much contact they had with the Behaviour Therapy Team and with REBILD. Some of the professionals had been involved in actively making referrals to the Behaviour Therapy Team, many others had not.

The health and social care professionals recruited were of many different levels of seniority, expertise and experience. They were all considered relevant to the study because they may all have exerted some degree of influence on the RCT. In many cases the professionals were already involved in the referral process, in most cases they had attended meetings and talks given by members of the research team. During the course of the REBILD trial it became clear that many health and social care professionals held strong opinions about REBILD. In some cases we had reason to believe that professionals had tried to bypass the trial in order to be able to refer their clients for behaviour therapy services. A detailed presentation of the sample characteristics will be presented in the following chapter.

Sampling was terminated upon reaching 'data saturation'. This referred to the point at which no more important themes were emerging from the interviews, and when there were no new insights and dimensions emerging through the themes themselves. The advantage of sampling three different groups of people is that it will invariably take much longer before data saturation is achieved, because there is a potential for a greater variety of opinions. The sampling process was undertaken concurrently with the data analysis procedure. This allowed for a continuous feedback loop between data analysis

and data collection. Themes generated through the data analysis could be used to guide the data collection and sampling procedure. Data collection ceased when no more themes were emerging from the data and all the potential avenues for different perspectives had been used up. A more detailed explanation of data analysis, including the process of reaching 'data saturation' is discussed in Section 2.3.

### **2.2.2 Qualitative data**

The process of data collection involved the use of semi-structured qualitative interviews. These were audio-recorded using an analogue Dictaphone, which was used with the participant's consent and permission. Two service user participants consented to be interviewed but refused permission to be audio-recorded. In these cases written notes were taken as a substitute, with the interviewees' permission. Audio-recordings were switched off if the interview was interrupted at any time, this happened frequently in workplace interviews because many of these offices were busy and the organisations were often short-staffed. The participant was formally reminded every time the Dictaphone was restarted. Interviews with carers and professionals lasted between 30 and 60 minutes, with an average length of 45 minutes. With paid staff, it was important to keep the interview under 60 minutes as all of these interviews were done during staff work schedules. Interviews with service users varied greatly in length, from 20 minutes to 90 minutes, again the average length of these interviews was approximately 45 minutes.

Semi-structured interviews were considered to be the most appropriate method of data collection for this study. This technique was selected over open-ended interviews because it allowed greater focus on key themes, which related to the research questions. Furthermore, it also allowed for a specific and standardised interview procedure across all participants, whilst giving participants the freedom to open up and explain their answers in detail.

Chapter 1 has outlined a number of studies which have used post-interview quantitative questionnaires to assess participant satisfaction and/or understanding. I have provided my critique of such studies in the light of previous work on lay theories and the therapeutic misconception (Appelbaum et



al, 1987). A systematic review of the literature and a working knowledge of how participants complete such questionnaires meant that I was sceptical of the potential usefulness of using purely quantitative methodology to answer a research questions such as mine.

I considered using focus groups instead of interviews for service users and health and social care professionals. The main advantage of this method would be to allow participants to share and develop ideas between themselves. This idea was discounted before data collection began for two reasons; firstly, the rapport and trust I had already developed with many of the participants appeared to favour a private interview method. Secondly, direct comparisons across the participant groups would be easier if the same method was employed.

Semi-structured interviews were conducted using standardised interview schedules (see Appendix 7.6) and vignettes (see Figure 5 and Appendix 7.7). These were equivalent across all participant groups. The interview schedules for carers and professionals were similar, and the vignette was identical. The interview schedule and vignette for service users were simplified and pictorial, but covered the same basic topic. Consideration was given to the placement of questions within the interview schedule. Opening questions were used to situate the interviewees in relation to the topics to be discussed. Carers and service users were asked about their involvement with REBILD, health and social care professionals were asked to describe their position and what it entailed. These questions allowed participants to warm to the interview process before they were required to answer more detailed questions. They were designed to be simple to answer and to build confidence before going forward to answer the more detailed questions. The remainder of the interview was based upon a series of propositions developed from a systematic literature review (see Chapter 1) and from my own experiences and observations as the field researcher for REBILD. The propositions identified four key areas which were addressed in the following order; participant's knowledge about the trial, opinions about research in intellectual disability, opinions about random allocation, and opinions about service assessment. All four propositions were developed in accordance with two independent bodies of literature;

observations made in previous research within intellectual disability (particularly in RCTs), and participant comprehension of RCTs.

The interview schedules consisted of main questions and probe questions. The main questions were deliberately open-ended and general. These main questions avoided 'leading' the interviewee too much into my own way of thinking. The aim was to elicit as much information from the interviewees as possible so that the interviewees could be seen to be responding in accordance with their own feelings, rather than the hunches of the researcher. Probe questions were slightly different. These were more specific and were often used to lead the interviewee down specific lines of enquiry that were of particular relevance to the study or that had not already been approached during the interview. These questions were used to elicit more detail about a topic, and sometimes used to rephrase a question differently to allow an interviewee to better comprehend it. The structure of the interview was not completely fixed. Certain questions could be omitted if the interviewee had already answered them inadvertently at an earlier stage in the interview. Probe questions were more often omitted if a line of enquiry had already reached its logical conclusion. The amount each interview followed the protocol was reliant upon my own discretion as the interviewer. This approach allowed the interview to follow a more natural conversational flow than a rigidly structured approach. It is noteworthy that my ability to conduct interviews with greater fluidity improved during the course as I became more experienced with the both the method and the questions themselves.

Both the interview schedule and vignette were reviewed by two independent speech and language departments who checked them for readability and accessibility. Previous research has shown that people with intellectual disability find it hard to understand abstract questions, time-related questions (Stalker et al, 1999), and questions that require the participant to draw upon their memory (Voss Horrell et al, 2006). Using open-ended questions with this population is a matter for debate. A literature review by Gilbert (2004) recommends against them, whereas Booth & Booth (1994) and Voss Horrell et al (2006) suggest that they can be used. The present study attempted to find a sensible medium. Open-ended questions were avoided wherever possible, but

in some cases it was necessary to ask participants to elaborate by asking such questions.

Therefore, interviews with service users differed substantially from those with carers and professionals. These interviews varied according to service users' level of understanding, as well as their preferred method of receiving information and material. The six service users that were interviewed for this study had varying abilities for reading and communication. Some participants felt more comfortable using the pictorial vignette. Some others preferred to use the standard interview schedule and vignette used for carers and health professionals. In both cases, probe questions were used to examine how well the service user understood the information given, much in the same way as for the other interviewees.

Participants were asked to look at a vignette after answering questions relating to their knowledge about the trial and opinions about research, but prior to answering questions about random allocation and equipoise. The purpose of the vignette was to remind participants about the specific method behind the RCT. I felt that this was a complicated abstract concept that participant needed to be reminded of before answering these questions. The placing of the vignette was significant and intentional. Each participant had already had the chance to describe their feelings and understandings about the study and their motivations for taking part, they could now reflect on the specifics of trial method and rationale. Figure 5 shows the vignette presented to carers and professionals, a copy of the pictorial vignette presented to some of the service users is available in Appendix 7.7. The audio-recording was stopped prior to presenting the vignette to the interviewees. The interviewees were then asked to read the vignette and to inform the interviewer when they had finished reading it. For service users, I took care to ensure that they understood the vignette. I went through the scenario with them step by step and asked them to explain what was happening at several stages in order to ascertain their level of understanding of the vignette, this variation accounts for the 20 to 90 minute length range of service user interviews. Following presentation of the vignette, the audio-recording was then re-initiated and the interview continued. This structure allowed participants to take a break during the interview if they wished.

**Figure 5** – Vignette for carers and professionals

**Scenario**

People with learning disabilities sometimes have problems controlling their behaviour. The local learning disabilities service provides support for people with behaviour problems. There is also a behaviour therapy service available in the local area which also provides support. The benefits of the behaviour therapy service have not been tested. A local psychiatrist contracts a research team to test the service.

The research team find 60 people to help test the services, they all have learning disabilities and problems controlling their behaviour. The research team assess the behaviour of all 60 people; they are then put into two groups of equal numbers. People in Group 1 will see the local learning disability service. People in Group 2 will see the behaviour therapy service as well as seeing the local learning disability service.

Every participant has an equal chance of being put into Group 1 or Group 2. A computer program is used to decide which group each participant will join. This computer program has no information about any of the participants. The research team assesses the participant's behaviour problems again after six months.

Each interview was concluded by providing each participant with a verbal summary of the main points that had been mentioned. This was done by feeding back these points to the interviewee and asking them if they felt as though it was a fair representation of what they had said. Participants were asked for any final comments before terminating the interview. Many participants made interesting comments and observations after the interview had finished. These post-interview comments were recorded wherever possible, with the interviewee's permission. This was done either by restarting the audio-recorder or by taking written notes. In order to help me remember and situate the interview better, I also took brief descriptive notes regarding the atmosphere of the interview, the appearance of the interview room, the nature of my relationship with the interviewee, and the relationship each person had with the

trial and with other trial participants. This aided my own memory of the events of the interview. Finally each participant was asked to complete a brief questionnaire which asked basic demographic details; age, ethnicity and educational level. Paid care workers and health and social care professionals were also asked about the nature of their post, their place of work, and the length of time they had worked with people who have intellectual disability.

Four pilot interviews were conducted with carers who had participated in the RCT. These interviews were audio-recorded, transcribed and analysed (though they were not included in the full, final analysis). The data was used to redefine the interview schedules, which involved removing some of the questions that could be seen as 'leading'. Three pilot interviews of the interview schedule were also carried out for health and social care professionals, somewhat later than the carer pilot interviews. No major changes were made to the schedules after the first three pilot studies, and these interviews were included in the final analysis. The minor changes made were recorded. The data collection phase began after the initial piloting had been conducted. Interviews with carers began in December 2006 and ended in May 2007. Interviews with professionals began in January 2007 and ended in August 2007. Interviews with service users began in December 2006 and ended in October 2007. The reason for the late collection of service user interviews was due to the fact that there was a scarcity of service users who were able and willing to take part.

No major revisions to the printed interview schedules were made after data collection for the main study was underway. However, the interview schedules did evolve over the course of the study; small revisions were made based upon the relative effectiveness of questions. A record was kept for every revision that was made. These revisions were made to ensure that the interview schedule was workable and appropriate; there were no changes to the major topics discussed.

However, throughout the data collection period I gained experience at interviewing the participants and became more knowledgeable about the subject area and interview schedule itself. The earlier interviews followed the structure of the interview schedule more closely. As I became more confident at

interviewing, I became more aware of the importance of conducting interviews with more natural conversational flow. Accordingly, the interviews began to take a more open format. Questions from the schedules were often asked in varying order in order to respond to the natural context of the conversation. This allowed the interviewee to talk more freely without interruption, and to produce richer, more varied data. As a consequence, questions from the interview schedule were often omitted as the interviewee may have already mentioned key points in a more natural conversational context.

### **2.2.3 Quantitative data**

A small amount of contextual quantitative data was collected in addition to the semi-structured interviews. The purpose of this data was to provide information about the characteristics of the sample. Clinical notes were audited for each service user. Information about the amount and type of input given by various services (psychiatry, nursing, occupational therapy) during the trial period was collected. The number of hours of behaviour therapy input was recorded for each service user and carer who was randomised to the intervention arm of the RCT. Additionally, clinical notes were audited for service users relating to each carer who was interviewed. Information was collected about health status, co-morbid psychiatric conditions, level and cause of intellectual disability, amount and type of psychiatric medication received, and whether the service user had experienced any major life events in the past 12 months.

Additionally, information about the service user's challenging behaviour was collected; this was taken directly from the data used in the REBUILD trial. The Aberrant Behaviour Checklist (ABC; Rojahn et al, 2003) was administered to carers and service users with sufficient capacity. This is a 58-item scale with five subscales relating to various domains of challenging behaviour. A person completing the ABC is asked to consider how that person has been within the previous four weeks. During participation for the RCT, participants were asked to complete the ABC at baseline, three and six month period. The ABC is a well validated psychometric questionnaire and it was used as the primary outcome measure for challenging behaviour in the RCT. However, for the present study, the results from the ABC were used merely for contextual purposes. Therefore ABC data was analysed in a simplified manner, the total scores across all five

sub-scales were calculated. They were then compared across the baseline and six month period for each participant. This obtained a basic measure of challenging behaviour, rather than a complex analysis of various sub-types of challenging behaviour, which was beyond the scope of the present study. Any comparisons using this data were not designed to produce a statistically significant result. However, it would provide an indication of how the challenging behaviour of each service user progressed during the course of the RCT.

#### **2.2.4 Ethics and Research Governance Approval**

In 2005, The REBILD trial received ethical approval from the Essex 1 Research Ethics Committee (formerly known as West Essex Local Research Ethics Committee). The RCT was funded by South Essex Partnership University NHS Foundation Trust. Ethical and Research Governance approval for the present qualitative study was gained in May 2006. Ethical approval for the latter study was granted from Essex 2 Research Ethics Committee (formerly known as South Essex Local Research Ethics Committee). Research Governance approval was granted from the Research Governance Steering Committee of South Essex Partnership University NHS Foundation Trust. Copies of the letters confirming ethical and research governance approval are presented in Appendix 7.4. The qualitative study was also partially funded by South Essex Partnership University NHS Foundation Trust, who contributed towards the UCL postgraduate course fees. For both studies, the sponsor had no role in study design, data collection, data analysis, or data interpretation.

### **2.3 Data Management**

I transcribed all of the interviews verbatim. I attempted to do this as soon as possible after each interview. This was beneficial because each interview could be recalled more easily and ambiguities on the audio-recording could be transcribed in accordance with both my field notes and my memory of the conversation. Transcribing every interview myself also allowed me to become familiar with the data, which served as good preparation for the initial stages of data analysis. Each transcript was reviewed for accuracy upon completion, and

was then entered into the N6 for Windows computer software (QSR International Pty Ltd., 2002). This is a piece of qualitative analysis software which essentially acts as a specialised database for qualitative data. Data within the database can be coded and categorised within a hierarchical structure. There is some debate about the use of computer software for analysing qualitative data (Peters & Wester, 2007). In my view, using the software was justified for two reasons, firstly from the perspective of data management; the size and variety of the sample. Secondly, from a rigour perspective; I would argue that the software would make it easier to track and record the progress of analysis over time.

### **2.3.1 Approach**

Two of the most common forms of analysis for interview data such as this are Grounded Theory (Glaser & Strauss, 1967) and Content Analysis. Both methods involve the categorising and coding of transcript data, but the two methods differ in their approach. Content Analysis follows a more 'top-down' approach which is closer to the positivist paradigm of quantitative research. Researchers start with an explicit framework of what they want to extract from the data, then they explore the data in accordance with this framework. Data can then be quantified by counting and tabulating the codes. Grounded Theory follows a bottom up approach, and has much in common with interpretivist epistemology (Goulding, 1998), and has often been referred to as 'emergent'. Within this approach, data is coded without reference to any explicit framework. The principle is that the themes and theories should emerge from the data itself. Grounded Theory is most useful when doing exploratory research rather than hypothesis-driven research. However, it should be noted that Miles & Huberman (1994) argue that all researchers have some preconceived framework; the distinction is whether or not they decide to make this framework explicit in the research process.

Initially, the basis for my analytical approach was more in line with a positivist paradigm, which was reflected in my more structured approach to interviewing participants. I aimed to use top-down approaches similar to those used in Content Analysis. For example, I envisioned a structured interview schedule in accordance with propositions found during field experience and previous



literature. This directly opposed the Grounded Theory approach. Practitioners of pure Grounded Theory may argue that consulting similar literature prior to data collection and analysis is undesirable, since it feeds expectations and biases (Hickey, 1997). However, as I continued to collect and analyse data I began to revise my interview technique in order to develop a more natural context to the interviews. I realised that the interviews worked more effectively if they had more fluidity and less pre-imposed structure. Thus I began to understand that a more emergent approach to analysis was required in order to do justice to the data. The interview schedules were re-organised to improve their fluidity and clarity, whilst the fundamental focus and questions remained the same. At this point I had already coded ten interview transcripts using a Content Analysis approach. I decided that this attempt at analysis was flawed, and it was archived.

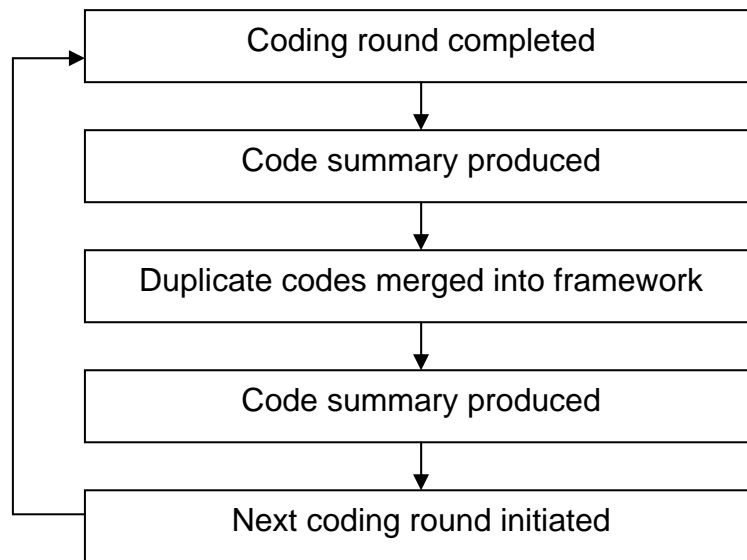
I created a conceptual diagram of possible links between themes. This diagram was based upon the initial analysis attempt. Miles & Huberman (1994) support the use of diagrammatic representations at various stages during analysis as a way of relating components to the broader picture. At first sight, this feature of my approach might appear to reflect a feature of positivism, which seems to contradict with the more interpretivist approach that I had decided to seek. However, it was a technique that I continued to use twice more throughout the analysis procedure to follow. I found diagrammatic representations useful for relating to my emerging interpretations. I returned to the methodological literature in order to seek a more appropriate approach to my analysis. The initial attempt at data coding was filed for reference purposes along with the conceptual diagram.

I investigated the Grounded Theory approach in more detail and decided to emulate the coding approach advocated by Strauss & Corbin (1990) in their modified version of Grounded Theory. I deliberately refrained from referring to my initial coding attempt when I approached the data for this second time. This new attempt at analysis began by performing 'open coding' on the transcripts. This involved line-by-line analysis of each transcript and coding each piece of data within N6 (QSR International Pty Ltd., 2002), giving each code an appropriate name. Open coding was done within the immediate context of the

surrounding text. These codes were created 'in vivo', within the transcripts themselves. No coding framework was used to guide this initial round of open coding. Sections of text often referred to multiple concepts or descriptions, so several codes overlapped in the text. Interesting ideas and analytic beliefs about codes were noted in the form of 'memos'. This round of coding was data-driven, not theory-driven. Open coding allowed for a more objective approach to the data, although preconceptions were to some extent inevitable. In practical terms, open coding allowed the analysis process to remain flexible. Codes were not forced into a coding framework at this initial stage. Instead, a coding framework would be allowed to evolve over the course of the analysis procedure.

Interview transcripts were coded in batches of six; this number had previously been recommended in a study of similar scale by Guest et al (2006). Coding transcripts in distinct 'rounds' provides a basis for making meaningful analytical progress whilst reducing the likelihood of being overwhelmed by the data. A 'code summary' was produced following each round. Codes were then scanned; duplicate codes were identified and merged together, the merging of duplicate codes created a more manageable and meaningful coding framework. Manageability was improved because there were fewer codes to organise. Meaningfulness was improved because the merged codes grew in size and substance, giving them more analytic relevance. A second code summary was produced following the merge procedure, and the process was repeated, as shown in Figure 6:

**Figure 6** – Flowchart demonstrating the coding process



The process of producing code summaries at regular intervals allowed the analysis process to be broken down into manageable sections. These regular code summaries also underpinned the creation of an audit trail. The purpose of the audit trail increases the transparency of the analysis process, and will be discussed in greater detail in Section 2.3.3.

The principle of open coding was useful for initial data analysis, producing a vast number of unlinked codes. Strauss and Corbin (1990) advocate the use of 'axial coding' following open coding in their modified version of Grounded Theory. Axial coding encourages theoretical abstraction from codes, relating codes together into themes. Codes are analysed in terms of 'conditions', 'actions' and 'consequences', for example:

- Why do certain events and beliefs occur?
- How do people act upon them?
- What happens as a result?

However, Glaser (1992) has criticised this approach, saying that it goes against the principles of pure Grounded Theory. Glaser has argued that themes should emerge from the data, and using a coding paradigm at this stage of analysis biases data interpretation due to researchers' biases. Nevertheless, I found it useful to employ axial coding at this stage of analysis. Axial coding helped in discovering relationships across codes and emerging themes. In particular I

used this approach to analyse the codes across dimensions. For example, participants' beliefs about research could be represented on a continuum. The point on a continuum for this theme could be moderated by another theme, which was also represented on a continuum. Relationships between themes could be illustrated this way.

My approach to analysis used elements from Strauss and Corbin's modified version of Grounded Theory (1990). However, the act of producing code summaries and frameworks is not consistent with pure Grounded Theory. This decision was intentional; a combination of emergence and coding frameworks was required, given the nature of the data. Emergence was required to capture the depth of the data, but the evolving framework was required to provide structure and guidance to the analysis process. This structure was essential because the research questions and the interview schedule revolved around specific areas of interest. Therefore the interviews and the coding process required structure. In many ways the approach I followed appears similar to the 'Template Analysis' approach developed by King (1995). Template Analysis represents an intermediate between Grounded Theory and Content Analysis; a coding framework is used to signpost data coding, rather than to direct it. The coding framework is revised constantly as it evolves during data analysis. This allows for new and previously overlooked codes to emerge into the coding framework, developing networks of hierarchical relationships between codes and themes. Nevertheless, my belief is that frameworks, codes and themes should be seen as a map to guide further analysis, not as an artificially enforced structure to limit analytical possibilities.

As previously mentioned, the coding framework was restructured following each coding round. However, a larger scale restructuring took place after six coding rounds (36 transcripts). The decision to restructure at this point was arbitrary and based upon personal judgement; the framework had become unwieldy and had lost clarity. First, the internal consistency of the contents of each theme was checked. Several themes had become accidentally generalised during the coding process, since they were referring to several seemingly unrelated subthemes. These themes were deemed to have lost their analytic usefulness. They were broken down and merged into other related themes, or created into

new themes. The relative importance of each theme was evaluated, since this also changed over the course of analysis. Each of the 36 transcripts was then re-read and re-coded according to the revised coding framework. The coding framework was then revised again; major inconsistencies were appraised and theme hierarchies were reorganised. This was a continuous process which occurred from this point until the end of analysis, with a constant feedback loop between data coding and the evolution of the coding framework. An excerpt from the coding framework is presented in Figure 7.

**Figure 7** – Excerpt of themes from the coding framework

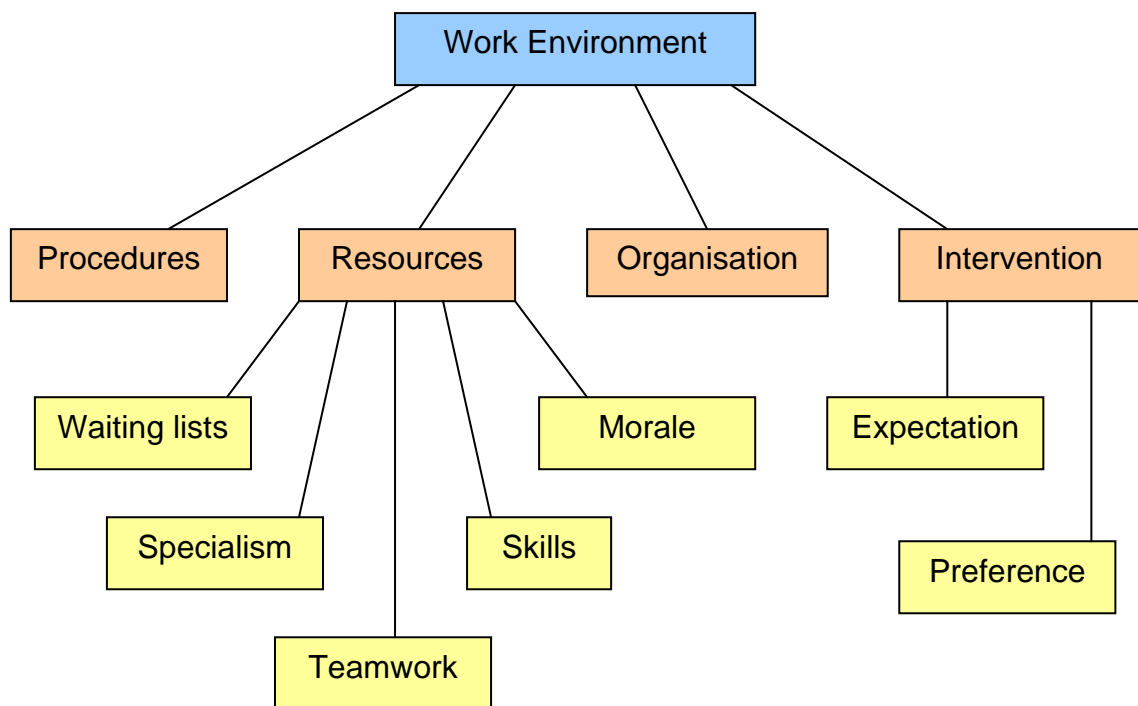


Figure 7 illustrates the hierarchical nature that the coding framework had developed at this stage of the analysis. In this example there are three levels of themes. The top level theme in this example is 'Work Environment', which shows four second-level themes and seven third-level themes. The coding framework evolved constantly throughout the analysis period. The full, final coding framework is presented in Appendix 7.9.

A more detailed analysis of themes was then conducted. Each theme was re-read and the main features and sub-themes were recorded. This process was akin to breaking the themes back down into smaller analytical units, and may

seem like a counter-productive step. However, themes were not broken down into in-vivo codes. The coding framework was left unaltered as themes were analysed holistically, as individual analytic units. Common sub-themes within each theme were noted and counted. Inferences about the content and relations of each theme were noted in this process of 'memoing'. Each major theme was analysed in this way. When this process was complete, it was clear that some themes replicated other themes. Duplicate themes were merged in the coding framework, and the memo was revised accordingly.

The remaining fifteen transcripts were then coded in three rounds; one round of six transcripts, one round of three, then one final round of six. Revisions to the coding framework were made following each coding round. The number of new themes and codes decreased, most new codes could be integrated into the existing framework within other major themes. After all transcripts had been coded, each of the themes in the coding framework was analysed in detail. Similar themes were merged together if they possessed no unique explanatory power. Conceptual diagrams were drawn, based upon the data analysis at each stage. These diagrams were used to guide the process of memoing. Analytical memos were then written in relation to the content and connections of each theme and sub-theme. Following analysis of all themes, the memo notes were recorded in a single document, organised by theme name. This document was read and re-read to provide insight about how data should be presented. The memo document was used as reference material for reporting the analysis in Chapter 4.

The write-up process was split into topic headings based upon the most important, most interesting and most relevant themes that had emerged throughout the analysis process. It became evident at this stage that many of the themes interlinked with each other in ways that had previously not been anticipated. In this sense, the process of writing was seen as an additional stage of data analysis. Many of the themes were renamed, particularly if their original names had been chosen during earlier stages of analysis and had since become inappropriate or misleading. The coding framework and the themes were revisited following the initial draft. Several themes seemed important either to the research question or to the context, but had not been written

appropriately into the draft. These themes were re-examined, if deemed relevant they were included or revised within the draft. This process provides an example of 'comprehensive data treatment'; each piece of coded data was accounted for in the final stage of analysis. Final conceptual diagrams were drawn to demonstrate the links between themes. These diagrams had evolved over the course of the study as a way of relating to the data, the final versions are presented in Chapter 5.

The quantitative and demographic data from the clinical audits was analysed in MS Excel and is presented using tables and bar graphs. No statistical tests of significance were conducted. The results from this data are presented in the following chapter as a pretext to the qualitative analyses. The purpose of this was to provide background information about the overall sample. The designation of the sample will now be discussed further.

### **2.3.2 Data Saturation**

Defining the point of diminishing returns was a key point of the study method. The benefits of collecting more data are limited by the data that has already been collected, and new insights cease to appear regularly. It is difficult to ascertain the saturation point of a data corpus. I relied upon the aforementioned audit trail to check how many new themes were arising with each coding round. Particularly useful were the code summaries generated after each round. It was also necessary to use common sense to determine the point at which no new insights arose. The data saturation procedure influenced the decision to stop recruiting and interviewing new participants.

Data saturation was calculated as follows: the code summaries for each coding round were analysed on two counts, the total amount of codes that had been generated, and by the number of themes. As illustrated earlier, each theme consisted of numerous 'tree' codes organised within a hierarchical coding framework. Additionally, there were a number of 'free' codes, unassigned to a particular category. The total number of codes was counted. The total number of top-level hierarchical themes was also counted. Table 4 summarises the number of codes and themes generated:

**Table 4** – Number of codes and themes generated after each coding round

<b>Coding round</b>	<b>Transcripts coded</b>	<b>Codes (n)</b>	<b>Themes (n)</b>
1	6	275	35
2	12	503	42
3	18	575	41
4	24	178	17
5	30	144	17
6	36	160	7
7	42	139	10
8	45	140	10
9	51	143	10

As seen in Table 4, the total number of codes increases rapidly during the first three coding rounds (18 transcripts). After the third coding round, enough data had been transcribed for broader themes to emerge. These themes became larger, more hierarchical, and encompass many codes. From this point on, the number of codes remained relatively stable. The themes became larger and more expansive, and the number of themes stabilised after the seventh coding round. The relative absence of new codes and themes after this point provides indication of data saturation.

Viewing data saturation numerically helped track and illustrate the process. However, identifying saturation was largely based upon intuition. Table 4 does not account for the variety of content within each theme. For instance, the majority of carer participants were interviewed early into the study for logistical reasons. The majority of the service users and professionals were interviewed later on. Later interviews with service users and professionals increased the wealth and depth of information within each theme without contributing many new themes and codes. This illustrates that the process of identifying data saturation was based upon careful examination of the audit trail and from knowledge of the data itself through repeated readings. Interviews with a wide



range of stakeholders would be necessary in order to maximise the depth of the themes. It was therefore justifiable to continue sampling participants beyond the mathematical saturation point. This was because there were several professions and positions within the intellectual disability services that had been underrepresented in the sample at that point. Participant recruitment officially ceased upon managing to collect interviews from a sufficient variety of stakeholders (i.e., gender, locale, profession).

### **2.3.3 Validity and Reliability**

There is widespread debate about the usefulness of traditional measures of validity and reliability in qualitative research. Some authors apply these terms to qualitative research (Patton, 2002). Others believe that qualitative research should fulfil a different set of criteria in order to maintain study quality (e.g., Driessen et al, 2005). Nevertheless, qualitative research includes a variety of methodologies. Some types of qualitative methodology, such as Content Analysis, are highly influenced by quantitative methodology. Other types of qualitative methodology are almost entirely emergent and do not strive for objectivity, such as Grounded Theory. The quality of qualitative research cannot be judged on a set of universal criteria. Decisions for maintaining quality need to relate to the study's methodological and epistemological background. The principles of validity and reliability should not be disregarded just because there are alternative ways for qualitative research to demonstrate rigour.

Lincoln and Guba (1985) devised an alternative set of criteria by which qualitative studies could be judged for 'trustworthiness'. These criteria are credibility, transferability, dependability and confirmability, and they were not radically different to the quantitative criteria of internal validity, external validity, reliability and objectivity respectively. However these latter concepts have become enshrined within quantitative methodology that now refer to relatively narrow concepts that may not be immediately applicable in qualitative settings. If nothing else, the process of renaming established criteria from quantitative methodology may allow more freedom for interpretation when they are applied within a qualitative context. The four criteria can be defined as follows:

- Credibility; whether findings are supported by data
- Transferability; how research findings can apply to a wider context

- Dependability; how the researcher accounts for the evolving processes of data collection, analysis and theory generation
- Confirmability; how well the analysis accounts for the data

Each of these four criteria is discussed in turn with regard to the present study. Credibility was addressed by summarising the main points of the interview to each interviewee, and asking a set of confirmatory questions. Each participant was asked whether the summary accurately reflected how they felt and whether they would like to add anything to the discussion. Furthermore, a second reader read a selection of the transcripts, giving a measure of inter-rater agreement. The second reader was my supervisor (a senior academic and clinician with expertise in the field of intellectual disability), who had also been involved with the REBILD trial. This procedure was conducted twice during the analysis process and once after the report had been drafted. The first instance of this was after the second coding round. At this point twelve transcripts had been coded, and the coding framework had reached a provisional state of development. Five transcripts were randomly picked using a random number generator, and the second reader coded these transcripts in accordance with the coding framework. I then met with the second reader to discuss inconsistencies and disagreements between coding, and inadequacies of the coding framework. Following this procedure, the framework was reworked in accordance with inter-rater agreement. One difficulty with this procedure was that the complexity of the full coding framework created by myself, who had analysed the dataset in full. The second reader did not have the same familiarity with the dataset, accounting for some inter-rater inconsistencies.

This problem was addressed following the analysis of all 51 transcripts. Ten transcripts were randomly selected, and given to the second reader. This time the second reader was asked to code the transcripts in accordance with a simplified coding framework. This simplified coding framework was non hierarchical, and included only the 'key themes' from the full coding framework. I identified key themes, based upon size, significance, relevance to the research question, and their links to other themes. Eighteen key themes were identified. These themes were easily detected since data collection had ceased, the coding framework was highly developed and I had gained a high level of

familiarity with the data. Each key theme was accompanied with a brief description, including reference to related themes and subordinate themes. This method gave the coding process greater flexibility, making it easier to detect meaningful disagreements between the two raters. Coding disagreements were marked on paper transcripts. Both readers then discussed the coding disagreements in relation to the simplified coding framework, with added reference to the full coding framework. Following this procedure, the full coding framework was revised to assimilate coding disagreements.

The second reader was consulted once more after the analysis had been drafted and reported. At this stage, the second reader checked the draft report for consistency, and checked that the themes reported had been supported sufficiently by the data. Again, I discussed any potentially problematic themes with the second reader until an agreement was reached. The report of the findings was then edited to incorporate the new changes. Following these changes, a second draft report of the findings was checked by the second reader.

The process of 'member checking' is seen by some as a good method to improve the validity of the data (Lincoln & Guba, 1985). Member checking involves giving interviewees an account of themes arising during interviews, then asking the interviewee to comment on it. Typically, this process requires the researcher to analyse the interview and then return to the interviewee at a later date. For this study, this process was done informally at the end of each interview; participants were given a verbal summary following the interview and asked whether they thought it was a fair reflection of their views. They were then asked for any further comments. Interviewees were not followed up at a later date after the analysis had been conducted, as advised by Lincoln & Guba (1985).

The reason for this decision was because it was arguable whether such a process would improve study rigour any more than the process I employed. Specifically, there is a potential problem with returning to interviewees at a later date. Data analysis is time and labour intensive. For this study, I conducted all data collection, transcription and analysis personally. The potential time

between interview and a reasonable level of analysis would be several months at least. Effectively, interviewees would be asked to comment upon an analysis of conversations they had had a long time previously. I believed that this approach could have been counter-productive because interviewees would view their comments out of context. This would also confuse the analysis process further. Instead, I chose to use the more immediate method of member checking described above, and I was encouraged to make intuitive summaries and crude analytical reflections in a real-time context. Likewise, interviewees could respond to these summaries in real-time. I felt that this approach was truer to the methodology used in this study, which aimed to describe a phenomenon in context.

Transferability was addressed by collecting information about the context in which the study took place. As has been described previously in this chapter, I collected demographic data about the interviewees. Information was gathered regarding the history and the context of the local area. These findings are partly revealed in the initial section of this chapter, but they will be explored more fully in the following chapter. The purposive sampling method for maximum participant variation improves transferability because the context has been represented in the sample to the greatest possible degree. This approach to analysis attempts to make theoretical inferences which are relevant to people in the wider context.

Dependability was addressed by discussing how the dynamic context of the study could affect the results. This problem was off-set by keeping a diary of all events related to the study. The diary entries tracked the changes in context during the course of the study. It also tracked any changes in the feelings and perspectives of me, the researcher. These feelings are a vital part of the context because I was the data collector, analyst and reporter. The diary was used as an aid to analysing and writing up the study. The reflexive account of the data analysis process is described earlier in this chapter. This account was revisited whenever the data analysis proceeded from stage to stage.

Confirmability was addressed by corroborating interpretations of the data with a second reader in the process described above. The second reader was

encouraged to play Devil's advocate during discussion of inter-rater agreement. The process of open coding intrinsically provided a good base for confirmability because transcript data was investigated line-by-line. This means that all of the data was accounted for, with theories and frameworks being built from the bottom-up before being analysed from the top-down. The coding framework was consistently revised until it accounted for all data within all the transcripts. Deviant and non-corroborating elements were identified through the data analysis process, and these 'outliers' will be accounted for in Chapter 4. These elements were sought out because they did not align with the major themes identified in the analysis. The whole process was underpinned by an audit trail. The audit trail has already been described earlier in this chapter, it allows the observer to examine and understand how the processes evolved, and how the data was approached at each stage.

## **2.4 Summary**

This chapter has described the method used to answer the research questions. This chapter began with demographic information about the geographical area and the various services available for people with intellectual disability. This included a summary about the Behaviour Therapy Team intervention and an appraisal of my own role as a researcher. The chapter went on to discuss the process of data collection, before discussing the process of data analysis. Care was taken to mention the problems and decisions faced during the course of the study. The chapter concluded by explaining the procedure of data saturation, and for ensuring reliability. The following chapters will present the data that was collected. Chapter 3 presents the data from the clinical audit, and describes the socio-demographic characteristics of the sample. Chapter 4 presents the findings from the qualitative analysis.

### **3. PRE-ANALYSIS**

This chapter is split into three sections and serves as an introduction for the qualitative data analysis, to be presented in Chapter 4. Section 3.1 describes the characteristics of the sample, factors such as age, ethnicity, occupation and relation to REBILD. Section 3.2 introduces the stylistic conventions that will be used whilst presenting findings. Section 3.3 introduces the themes that arose from the analysis, which will form the basis for the data to be presented in Chapter 4.

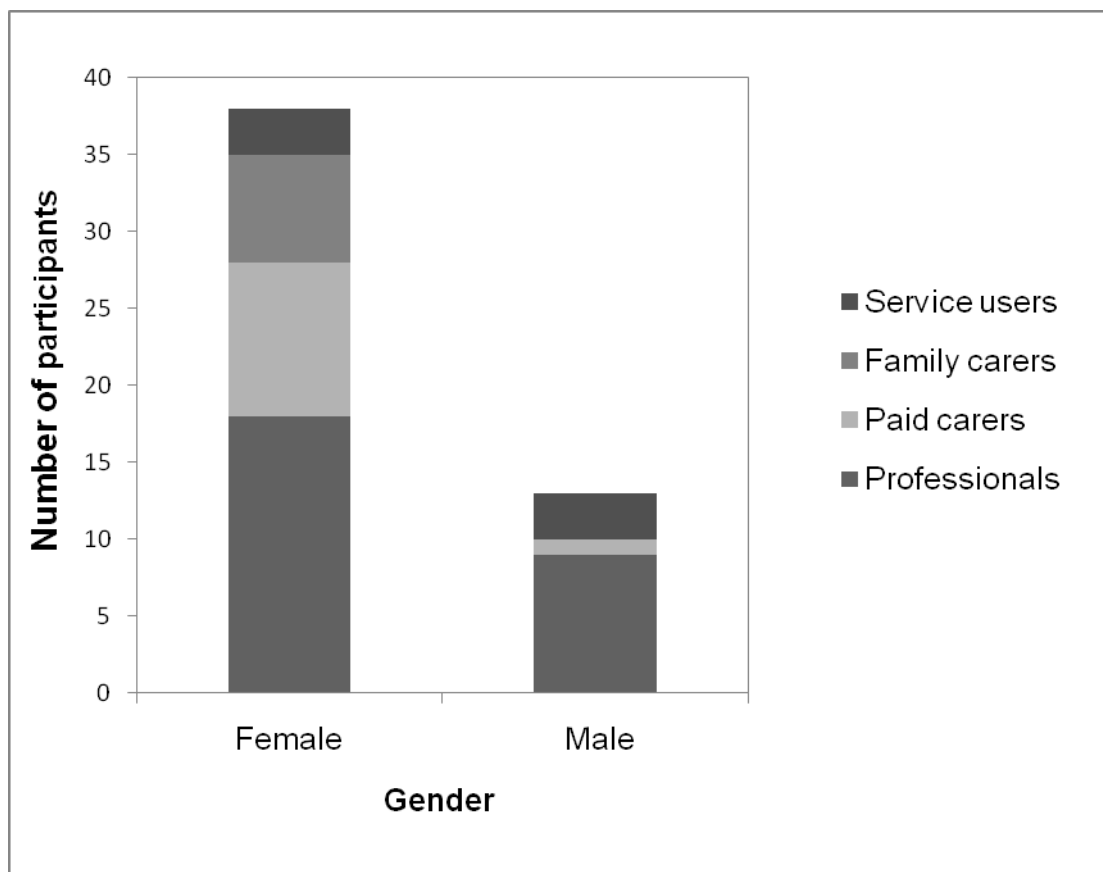
#### **3.1 Sample demographics**

The following section will present the socio-demographic trends of the sample population. First, I will present participants' ethnicity, age and gender characteristics. This will be followed by details about employment, service user health and mental health and medication use. Carers' and professionals' educational level and employment capacity will be described. Finally, referral trends to the Behaviour Therapy Team during REBILD will be described.

The ethnicity of the overall sample (n=51) was 86% White (n=44), and 78% White British (n=40). Three interviewees were of South Asian origin (6%), another three were of Chinese origin (6%), and one interviewee described their ethnicity as mixed White and Asian. All six of the service users who interviewed for the qualitative study were of White British origin. It is noteworthy that the proportion of people from non-white ethnic backgrounds interviewed for this study is significantly larger than for the proportion within Essex County (2.9%; Office for National Statistics, 2001). However, the specific region of the county where this study took place has a much higher proportion of people from ethnic minorities, for example, the unitary authority of Thurrock has 8.2% population from non-white backgrounds (Office for National Statistics, 2005). In this context, the high number of people from non-white backgrounds seems more representative.

Figure 8 shows the differences in gender distribution across the groups of interviewees. Equal numbers of male (n=3) and female service users (n=3) were interviewed, but the majority of the overall sample was female (75%). This obviously fails to represent the population as a whole, but it does reflect the high proportion of females working within services for people with intellectual disability. The figure shows that a greater number of females were recruited from the family carer, paid carer and professional categories. The greatest difference in gender distribution is shown in the family and paid carers interviewed; seven mothers, no fathers, 10 female paid carers, one male paid carer. This could be seen to represent a skewed sample, though residential care homes are predominantly female staffed. This possibly represents the fact that females seem more likely to take on the role of primary carer for a child with intellectual disability.

**Figure 8** – Gender of participants



The most significant fact shown in Table 5 is that there were a large number of interviewees from the professional, paid and family carer categories who were above 50 years of age. By a large margin, the most numerous category of

interviewees was the 51-60 age group. In particular, the family and paid carer participants were skewed in favour of this age group. By contrast, the service user interviewees were younger; none of them were over 40 years of age.

**Table 5** – Age of participants

Age group	Service	Family	Paid carer	Professional	Total
	user	carer			
22-25	0	0	1	0	1
26-30	3	0	1	3	7
31-40	3	0	1	5	9
41-50	0	0	2	7	9
51-60	0	6	5	10	21
61+	0	1	1	2	4

The large number of family carer, paid carer and professional interviewees aged 50-61 is notable. For paid carers and professionals, this may reflect the amount of experience they had of working with people who have intellectual disability. Each paid carer and professional interviewee was also asked how long they had worked with this population, and this information is presented in Table 6. This data shows that this sample of paid carers and professionals varied in their level of experience. The range in experience for professionals was wider than it was for paid carers, and four professionals had worked with people with intellectual disability for over 30 years.



**Table 6** – Years of experience

Years of experience	Professional	Paid carer	Total
1 to 5	4	1	5
6 to 10	5	3	8
11 to 20	6	5	11
21 to 30	7	2	9
31 & over	4	0	4
n/a	1*	0	1

\* – Only occasional contact with people with intellectual disability

### 3.1.1 Service users

The six service users interviewed for the qualitative study had a higher level of ability and independence than the majority of the RCT participants. Two participants were randomised to the control arm of REBILD, and the other four were randomised to the intervention arm. Two service users were living independently in their own accommodation. Three were employed, one full-time and two part-time. None of the six people had any problems with ambulation, and two had driving licences. The amount of interaction with mainstream society within these six participants was not representational of the REBILD sample, because all six were able to go out unassisted. In addition, four of these interviewees suffered from a variety of physical health problems; two reported a history of epilepsy, two reported having skin conditions, one reported having a hormonal imbalance. In three cases the cause of intellectual disability was recorded as unknown, in the other three cases the cause was identified as trauma at birth or infection in infancy. Within the REBILD sample as a whole (n=63), unknown causes of intellectual disability were most common (accounting for 59% of the sample).

With regards to medication, five of the six service users were taking regular medication, of whom, four were receiving medication for psychiatric conditions. Of these four service users, three were receiving anti-depressants, two were receiving anti-epileptics, one was receiving anti-psychotics, one was receiving anti-anxiolytics, and one was receiving a mood stabilising medication. Service

user mental health varied; four had been previously diagnosed with a depressive disorder, three had been previously diagnosed with an anxiety disorder, two had been diagnosed with both depression and anxiety, and four had been previously diagnosed as having autistic traits. All diagnoses and classifications were done by a local psychiatrist.

The problems experienced by service users within the REBILD study were complex and multi-faceted prior to participation in the RCT. All six service users had experienced difficult life events within the preceding year, and half reported three or more negative life events over this period. Four of the service users displayed a reduction in challenging behaviour over the trial period. This was recorded using the primary outcome measure for the REBILD trial, i.e., the total scores as measured by the Aberrant Behaviour Checklist over a six month period. The implication is that these service users had a complex interplay of physical, mental health and complex needs.

### **3.1.2 Family carers**

Seven family carers were interviewed, all mothers. Four were educated to GCSE level or equivalent (of whom two also had vocational qualifications); the remaining three had no formal qualifications. Another potential complicating factor for influencing stakeholder experiences was the allocation of service users within the RCT. With regard to allocation through randomisation; four of the family carers were speaking on behalf of people who were randomised to the control group, and the remaining three were speaking on behalf of people who were randomised to the intervention group.

Three family carers saw an overall reduction in challenging behaviour for their service user over the six month trial period; the remaining four experienced an increase in challenging behaviour with their service user. These differences were measured by comparing the scores from the primary outcome measure between baseline and six months. These differences were not statistically significant and are quoted here only to provide an indication of sample characteristics.

### **3.1.3 Paid carers**

Eleven paid carers were interviewed; six were managers from residential care homes (of whom two were also qualified nurses), two were staff at the service users' regular day centre, one was a support worker from a private care organisation, and one was a residential carer in a non-managerial position. One further participant worked in NHS long-stay inpatient services, and had known the corresponding service user for many years. Three were educated to undergraduate level (one of whom also had a vocational qualification), one was educated to 'A' Level equivalent, four were educated to GCSE level or equivalent (two of whom also had vocational qualifications), two had vocational qualifications only, and one had no formal qualifications. Paid carers varied in the amount of experience they had with people with intellectual disability, from 1 – 24 years (mean=13.4 years).

With regard to allocation through randomisation; four of the paid carers were speaking on behalf of people who were allocated to the control group, and seven were speaking on behalf of people who had been allocated to the intervention group. Nine paid carers saw an overall reduction in challenging behaviour for their service user over the six month trial period. One experienced an increase in challenging behaviour with their service user, and one remaining service user had no change in total challenging behaviour. This implies that the level of challenging behaviour displayed by the majority of these service users did improve over time, during their participation in the RCT.

### **3.1.4 Professionals**

The full sample of professionals (n=27) consisted of 20 participants who were employed by health-based organisations and seven participants employed by social care organisations. Fifteen participants were working as nursing staff of various grades, ranging from support workers to nurse managers. Seven professionals were engaged in social work activities, and their grades ranged from assistant social worker level to senior social care management. The remaining professional participants from the healthcare sector included two psychiatrists, one psychologist, one speech therapist and one occupational therapist. Only one of the participants did not work full-time in the intellectual

disability service. This composition resembles the total proportion of all staff employed in each capacity across the local area.

Professionals' level of education varied considerably. A large proportion (n=19, 74%) had been educated to degree level. Just under half were educated to postgraduate level (n=13) and a further seven interviewees possessed undergraduate degrees. One was educated to 'A' level equivalent, two were educated to GCSE level, and one had no formal qualifications. Additionally, four people possessed vocational qualifications. Broadly speaking, the educational level of professional participants was higher than that of the paid carer participants, and much higher than that of the family carer participants. Additionally, the professionals varied widely in the amount of time they had worked with people with intellectual disability, this ranged from 2 – 36 years (mean=17.6 years).

Professionals typically worked within multidisciplinary intellectual disability teams. Most of the professionals (n=21, 78%) were exclusively associated with one of the five community intellectual disability teams, whilst the remaining six professionals worked across the wider NHS Trust organisation. These community intellectual disability teams were delineated geographically, providing input for a population of service users with intellectual disability within their local area. There were five community intellectual disability teams across the larger geographical area, and each of these teams made referrals for service users to the intervention team during the RCT.

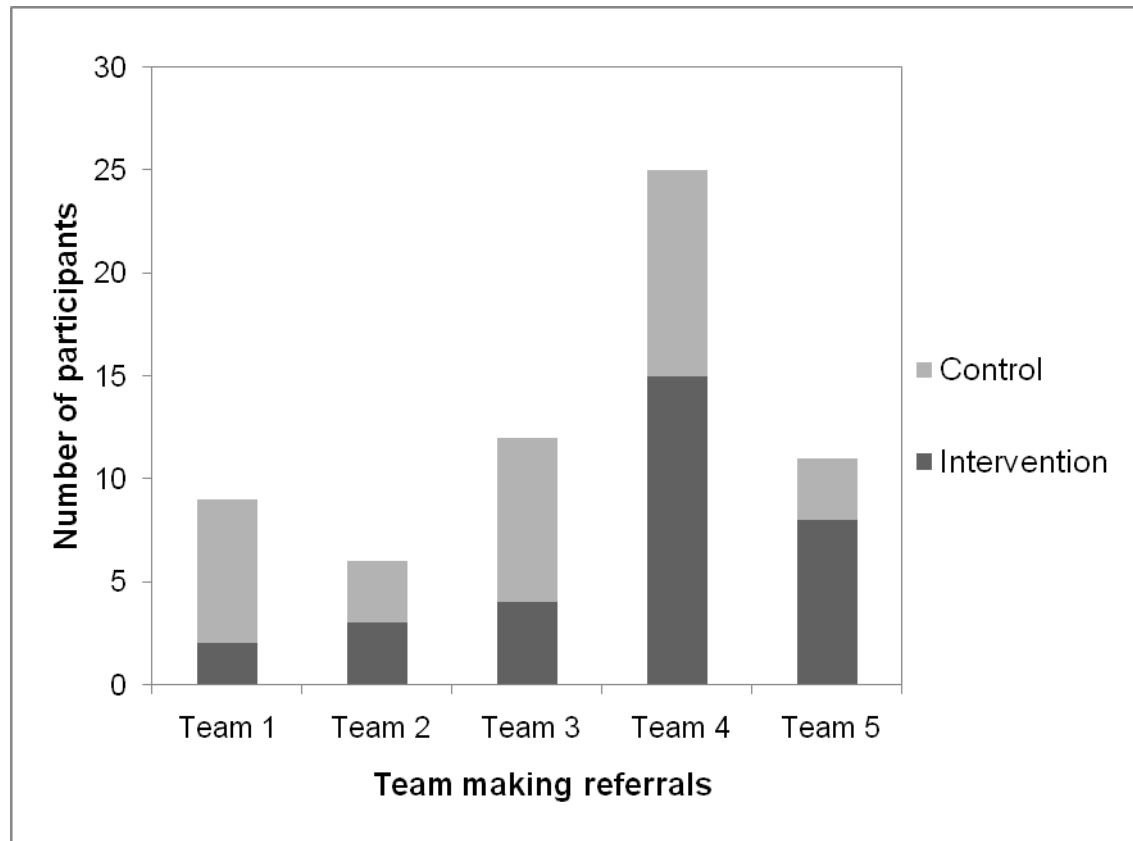
Figure 9 shows the number of professionals interviewed from each of the five community intellectual disability teams. This figure also highlights how some teams made more referrals than others, Team 4 made a larger number of referrals to the intervention during the RCT than any of the other teams. By contrast, Team 2 made a much smaller number of referrals for intervention. The probable reason behind this was that the intervention team had originally been initiated within the two areas surrounding Team 3 and Team 4. These teams had been making referrals to the intervention team for several years prior to the initiation of the REBILD trial. By contrast, Team 1 and Team 2 had historically worked under a different system. These two teams had been only been able to

refer to the intervention team for a much shorter period of time before the RCT began. Therefore, historic variations in service delivery across the different teams probably influenced these differences in referral patterns to the intervention team.

Furthermore, Figure 9 shows how the randomisation process affected each of the five teams. Allocation was randomised equally across the entire REBILD sample, a total of 32 participants (51%) were randomised to receive input from the intervention team immediately after agreeing to participate in the trial. The remaining 31 participants (49%) received no input from the intervention team during the six month trial period. Statistically, the randomisation procedure distributed participants equally to the intervention and control groups.

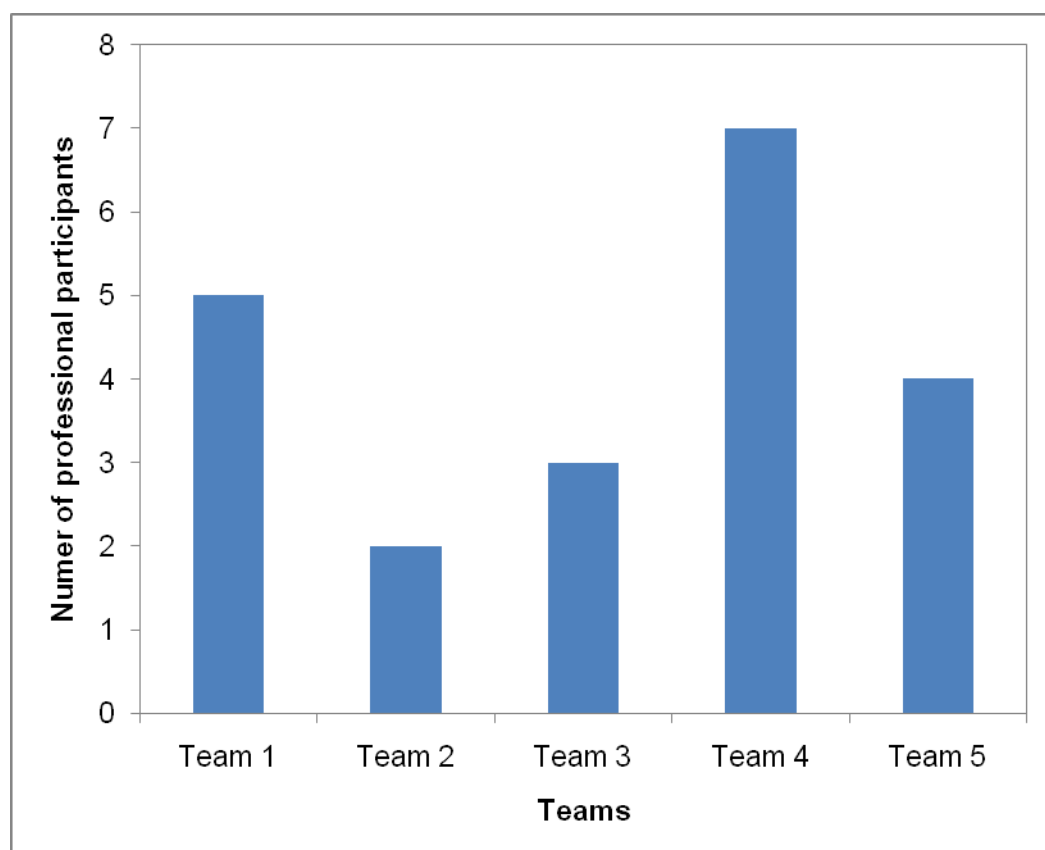
However, the impact of randomisation for each of the five teams may have differed. For example, Figure 9 shows that Team 1 and Team 3 had a greater proportion of referrals allocated to the control group than to the intervention group. By contrast, most of the service users who were referred by Team 5 were allocated to the intervention group. These figures may highlight subjective differences in how people from the various teams felt about the equality of the randomisation process. Subtle differences in the allocation ratio between the teams may have implications for how people within those teams perceived the impact of randomisation upon service user referral patterns.

**Figure 9** – Referrals to the intervention and allocation by randomisation



The points raised above should be related to the data presented in Figure 10 below. This shows the sample distribution of the 21 professionals associated with the five multidisciplinary teams. To a certain extent, this distribution represents the total number of referrals made by each team. For instance, the highest numbers of professionals were interviewed from Team 4, which also contributed the highest number of participants in the RCT. Also, only two professionals from Team 2 were interviewed, as this team provided the smallest number of RCT participants. Still, Team 3 is underrepresented in comparison to Team 1.

**Figure 10** – Number of professionals interviewed from each team



There are possible implications to this sample distribution. For instance, in Team 1, two out of nine service users (22%) participating in the RCT were randomised to receive input from the intervention team. In contrast, in Team 5, eight out of eleven service users (73%) participating in the RCT were randomised to receive input from the intervention team. For professionals working within these teams, these unequal allocations may conceal the equality of random allocation across the entire sample of RCT participants. In consequence, interviewees from the professional teams may relate to the RCT from different starting points. This may be affected by the number of service users within each team who were randomised to control and intervention groups. This is worthy of reference when presenting the data in Chapter 4.

This presentation of the demographic and clinical characteristics of the sample has provided a context for the more detailed exploration of the interview data to follow. As has been shown, interviewees represented a wide spectrum of stakeholders within the local community who were involved to some extent with people who had intellectual disability. Due to the difficulties of interviewing

participants with more severe intellectual disability, this sample does not attempt to exhaustively represent those participants who participated in REBILD. The next section of this chapter will introduce the conventions to be used throughout the presentation of the results.

### **3.2 Presentation of analyses**

The qualitative method used in this study has been outlined in the previous chapter. This method was chosen to illuminate interviewees' experiences of an RCT. Chapter 4 will present quotations from interviewees, from each participant group in turn. Each interviewee has been assigned a gender appropriate pseudonym to conceal their identity. These pseudonyms will be used at all times throughout the thesis. Detailed information for each individual interviewee is presented in Appendix 7.8. Care has been taken to disguise any identifying information.

Presenting quotations from interviewees requires adherence to conventions, which relate to the researcher's philosophical and methodological standpoint. Analyses will be presented in narrative form. Presenting interview data logically and legibly is a challenge of qualitative data analyses. A linear, narrative structure attempts to counter these problems, presenting themes sequentially. However, narrative structures present problems because the data analysis process is non-linear. Instead, themes arise and interlink with each other in multi-faceted, intricate networks. Linear presentation of findings does not capture complexities of data analysis; presenting interview data within a narrative structure imposes artificial structure on the data.

Quotes from interviewees are presented to illustrate and develop themes. Quotes are given in accordance with verbatim transcripts where available. In the case of two service user interviewees, written notes were taken instead of audio-recordings. All quotes are presented in quotation marks, preceded by a reference number. The number preceding the dot refers to the chapter or sub-chapter number (e.g., 3, 4a, 4b, etc); the number following the dot refers to the sequential position of the quote within the chapter or sub-chapter. The quote is



followed by the name and the stakeholder capacity, where this is not self-evident, for example:

Extract 3.1 – “Obviously you’ve still got the caring side of it but yeah you’re not emotionally involved with it” (Philippa, paid carer)

Interviewees are quoted to provide evidence for themes within the narrative. Quotes are preceded by a short introduction and followed by a short explanation which reveals the parts of the quote that are relevant to the specific theme being discussed. The majority of quotes are presented in uninterrupted form, but many were trimmed to avoid confusing the narrative. Occasionally, quotes are presented where the speaker has been interrupted and has resumed. The purpose of this was to maintain the integrity of the narrative. For example, an interviewee may have been talking about one topic, stopped, and resumed conversation on the same topic moments later. Trailing dots within square brackets ‘[...]’ is used to signify this.

Significant pauses in the conversation quotations are narrated with three trailing dots ‘...’ without brackets. The length of the pause was not recorded and reported since it was deemed unnecessary outside of the realms of Discourse Analysis. Interviewees’ own emphases within each quote is denoted through the use of *italics*. Repeated words and other spoken idiosyncrasies such as ‘ah’, ‘umm’, ‘err’ and ‘erm’ have been removed in the majority of quotations, for example:

Extract 3.2 – “Only..only within this trial I haven’t done, uh otherwise w..we might have been included” (Marie, nurse)

Would be presented as the following:

Extract 3.3 – “Only within this trial I haven’t done, otherwise we might have been included” (Marie, nurse)

This was done simply for ease of reading. Spoken idiosyncrasies and pre-verbal utterances were not coded into the analysis process. In many cases

these utterances may seem to occlude the true meaning of the speaker. Some service user interviewees spoke with many pre-verbal utterances, possibly due to the nervousness of being audio-recorded. Presenting these quotes in raw form would make the service users seem less literate than they actually were. Nevertheless, there are exceptions to the presentation of pre-verbal utterances. Occasionally a pre-verbal utterance does appear to have some meaning within the context of the quote that surrounds it. Examples of this occur to show that an interviewee is demonstrating a thought process or a moment of uncertainty. In these cases, the quote was left intact, such as the following:

Extract 3.4 – “whether what they do is err, how do we say that, is *valuable* to the clients” (Andrea, nurse)

Occasionally, interviewees are quoted in places where they may reveal the names of third parties. To protect anonymity and confidentiality, an ‘X’ is used to replace the names of real people in these cases. At other times, interviewees may refer to unclear abbreviations whose meaning is obvious to the interviewee but not to the reader. Square brackets will be used in place of the missing word, to clarify the meaning of the sentence, for example:

Extract 3.5 – “I think this [vignette] is pretty fair” (Craig, service user)

The aforementioned conventions are used to make raw conversational data more presentable and more analytically useful for the purposes of this study. This was not a Discourse or Conversation Analysis, therefore the emphasis here was on maximising the meaning of statements, rather than the individual words and the rhythm of the sentences. Nevertheless, care has been taken to present the data in a format that is both true to interviewees’ original meaning and legible for the reader. Adherence to quote conventions within a narrative structure sacrifices data purity, but such sacrifices are necessary in order to present the data to the reader. Chapter 4 is broken down into four sub-chapters (4a, 4b, 4c and 4d). These sub-chapters will relate the data of service users, family carers, paid carers and professionals respectively. Chapter 5 will interpret the findings presented using a theoretical, non-linear structure. This will allow cause and effect relationships between themes to be described.

### 3.3 Main themes

Themes were appraised throughout the analysis process. Chapter 4 will present these main themes across four sub-chapters from the four groups of participants (service users, family carers, paid carers, and professionals). This final section of the present chapter describes how these themes developed.

#### *Disadvantage and labelling*

This theme arose from various comments about how the service users may feel in relation to wider society. In particular, it relates to feelings of being disadvantaged within society. A small number of the interviewees mentioned the Social Model of Disability (Oliver, 1983), and how people with an intellectual disability may be labelled from an early age. This labelling may then link into further disadvantage within society.

#### *Funding and Resources*

This theme relates to a wide spectrum of comments made by the majority of stakeholders. Themes relating to funding and to the provision of resources established prevalence at an early stage of the analysis. The majority of the comments related to the lack of funds available for resources for people with intellectual disability. More specific comments discussed the possible sources of funding, the cyclical availability of funding, and the difficulty of keeping faith in services that have been under-resourced.

#### *The work environment*

This focuses on the structure behind the services that are available for people with intellectual disability. Originally, this theme centred upon carer and professionals appraisal of their own work environment and job roles. The majority of this discussion centres on professional working environments within the local area, although some regional variations are also mentioned. This theme also includes stakeholders' perceptions of the personal characteristics that people working within these services need to have; the ability to co-operate within a team, to maintain morale, to be able to share staff skills and specialist knowledge with others.

### *Seeking help and support*

This theme has been derived from several different sub-themes, based around problem solving behaviour, help seeking behaviour, and conceptions about the ability and complexity of service users. Carers, service users and professionals may all adopt help seeking strategies to overcome potentially difficult situations. Stakeholders discuss the complexity and individuality of problems that can arise within this population. The process of seeking peer support, the need to be self-sufficient, and the adoption of trial and error strategies are also considered, along with the barriers to seeking help and support.

### *Opinions about research*

As the title of this theme suggests, this is a wide-ranging topic that discusses stakeholders' opinions about research. This relates to general research processes, how they are conceptualised, and opinions about how research should be applied within the context of people with intellectual disability. Interviewees discussed the important qualities that they believe research should possess, including the importance of practical outcomes.

### *Research outcomes*

This is an extension of the previous theme, which specifically focuses on the topic of outcomes. The theme described interviewees' interest in the outcomes of research, and their beliefs about how research may be disseminated and publicised.

### *Research within services*

This relates to the culture of research in services for people with intellectual disability, and the need for future research. Participants show an interest in improving services in this area, and the procedures of service monitoring and service evaluation are discussed, both internally and externally. The principles of evidence-based practice are described by a minority of professionals.

### *Communication and understanding*

This theme stems from several important sub-themes relating to the unique challenges presented to those working with people who have intellectual disability. The problems of communication and understanding were often

mentioned. Carers showed concerns about how they could objectively understand what a service user may mean. Interviewees talk about the possible aids and strategies that may facilitate communication.

#### *Informed Consent (and approaches for gaining it)*

The history of this theme draws from discussions about the difficulties of involving people with intellectual disability in research. The sub-themes presented here document the problems associated with gaining informed consent for various procedures involving people with reduced capacity. Several different approaches were found, including the use of multi-disciplinary meetings, and the application of the standard of 'best interests'.

#### *Perception of clinical research*

These stem from beliefs about clinical drug testing. The ethics and problems arose, along with the problems of potential side effects. Much of this was in response to a highly publicised drug trial that had gone wrong in the UK (see St Clair, 2008). This incident occurred several months before the interviews were conducted.

#### *Terminology*

This theme included interviewees' perceptions of the words 'random' and 'trial', as each participant was asked on the interview schedule. Various conceptions of the word were considered.

#### *Method*

This theme arises from the discussion of terminology. It represents a complex set of themes that detail what stakeholders' believed about the RCT process. Within this, the trial rationale and procedure are discussed, and the potential reasons for conducting a trial in this way.

#### *Fairness*

This theme deals with stakeholders' particular concerns about the randomisation procedure, and whether they perceived the situation as fair or unfair.

### *Preferences*

Much of the content of this theme was originally based upon discussions of professional working environments. This arose because of the preferences that participants and other stakeholders showed during the RCT. Stakeholders tended to prefer being allocated to the intervention group, rather than the control group. These preferences appeared to be stronger in times of emergency.

### *Motivation*

This theme contains information about how and why people decided to participate in the RCT. Altruistic and self-interested motivations are not uncommon. The themes herein evolved from an earlier theme containing the perceived motives, outcomes and benefits of the RCT.

### *Benefits*

This relates to the *motivation* section outlined above. The information contained here documents how stakeholders feel about the potential outcomes of the RCT. Interviewees' reflect on the benefits and costs in context. This arose from a commonly asked question on the interview schedule that was designed to elicit this information.

### *Approach*

This represents discussions surrounding the applicability of RCT approaches. This encompasses ideas about reductionism and quantification of outcomes, which is in turn related back to perceptions about the complexity of research in this population. This stems from complaints about the RCT method in terms of difficulties envisaged with practicalities and ethics.

### *Access*

Interviewees air their opinions about their ability to access the intervention during the trial period. This section evolved from a discussion about the impact of the RCT, and the practical difficulties therein. It was also influenced by another theme that had highlighted the conflicts of randomising participants and prioritising patients who were randomised to receive standard treatment only.

### *Safeguarding*

Interviewees thought of various ways to reduce the impact of the RCT over the course of the trial period. This was seen to be particularly important in pragmatic settings. These 'safeguards' aim to build more flexibility into the RCT design, and interviewees may see them as reducing practical and ethical problems. This theme has roots in a theme about the ethics and safety of the RCT.

### *Frequency of themes*

These themes represent the most important of the themes to be derived from the analysis. A significant number of interviewees contributed to these themes, as shown in Table 7.

**Table 7** – Number of interviewees contributing data for each topic

<b>Theme</b>	<b>Service Users</b>	<b>Carers</b>	<b>Professionals</b>	<b>Total</b>
Disadvantage / labelling	3	6	12	21
Funding / resources	2	13	23	38
The work environment	3	18	27	48
Seeking help and support	4	16	19	39
Opinions about research	6	18	27	51
Research outcomes	3	15	23	41
Research within services	1	15	27	43
Communication / understanding	5	13	25	43
Informed consent	5	16	26	47
Perception of clinical research	4	16	24	44
Terminology	5	17	26	49
Method	5	14	27	46
Fairness	5	16	13	34
Preferences	3	15	25	43
Motivation	3	14	3	20
Benefits	5	16	27	48
Approach	5	18	27	50
Access	4	9	24	37
Safeguarding	1	1	17	19

Table 7 shows how these core themes have basis in the data, for example, all interviewees had contributed their ‘opinions about research’ at some point during the interview. These values serve as guidelines only, as some interviewees contributed far more than others on specific topics. It should also be noted that many of the themes relate to questions and probes from the



interview schedule. This accounts for the high numbers of interviewees contributing to certain themes.

### **3.4 Summary**

This chapter has functioned as a preliminary to the presentation of results. Demographic information of the sample was presented in Section 3.1, showing the commonalities and idiosyncrasies of the sample. Section 3.2 described and justified the conventions of data presentation. Section 3.3 introduced the main themes from the analysis that will be discussed in Chapter 4.

Chapter 4 presents the qualitative data from service users (4a), family carers (4b), paid carers (4c) and professionals (4d). Family carers have been separated from paid carers for the purposes of analysis because of the different context in which they approach the trial situation. The data will be presented in a narrative. Following on from this, Chapter 5 will summarise the main findings and present a theoretical framework of participant conceptions of RCTs within the community surrounding people with intellectual disability.

## 4. RESULTS

This chapter forms the core of the thesis. The results from the interviews with each set of participants; services users, family carers, paid carers and professionals, have been analysed in turn. The chapter is therefore split into four sub-chapters, 4a will describe the results from service users, 4b will be dedicated to family carers and 4c to paid carers. Lastly, 4d will describe the experiences of professionals, comprising the largest single sub-chapter.

There were a number of common themes that arose between the different sets of participants. There was a shared feeling that people with intellectual disability occupy a place of relative disadvantage within society as a whole. Related to this, there was a perception that insufficient financial resources were available to optimally support this population. People with intellectual disability were therefore in danger of being seen as somehow set apart from mainstream society, rather than successfully integrated. Across the participant groups, there was the perception that people with intellectual disability were likely to need help and support at some time during their lives. This was felt to be especially difficult within the challenging environment so far described. In this context, views on research were almost unanimously positive, especially when the research would have practical or applied purpose. However, many highlighted difficulties in communication and in completing the informed consent process, which made research more difficult.

There were varying degrees and nuances to which the different participant groups elaborated within each of these common themes. There were also a number of themes that were developed in some participant groups without being developed in others. Thus, the analyses for separate participant groups are presented separately throughout this chapter.

## 4a. SERVICE USERS

This sub-chapter will attempt to describe the service user perceptions of trials with people with intellectual disability. It will discuss the findings that arose during the interviews. Much of the data was related to service users' own perceptions of their lives and how they related to the world, including the services they received.

### 4a.1 Perceptions of disability

Perhaps unsurprisingly, one of the most obvious elements from the interviews was the discussion of labelling that service users experienced. This immediately strikes as an important piece of contextual information to bear in mind when recruiting service user participants for an RCT.

Extract 4a.1 – “they’ve put me under learning disability.

They’ve...instantly put me under and I think it’s *wrong*...and so I don’t get to know what services are out there for mental health because I’m under learning disability. I think they’ve labelled me, whereas they shouldn’t label people [...] *every single person* is different. They’re not the same *at all*. Erm, I can relate to quite a few people...and we’re all three of my friends all completely different” (Elizabeth)

Here, Elizabeth is describing how the various labels she has received have affected her. She appears to have strong feelings against the labels she has received. Here she differentiates between the two teams that could provide care for her, the ‘mental health’ team and the ‘learning disability’ team. She suggests that she has been unable to access mainstream mental health services because of her disability. This attitude indicates an appreciation of her personal complexity and the fact that a label does not give an accurate picture of her identity. It is worth bearing in mind that even people with mild forms of intellectual disability can suffer labelling from quite a young age:

Extract 4a.2 – “when I was at school the attitude the school had was ‘leave him alone and he’ll do it in his own good time’...now that is not

how they do it now...this is probably the problem why I'm like the way I am now." (Martin)

Martin relates labelling to the difficulties he had experienced with the attitudes of teachers when he was at school. He feels that the school system inadequately supported him and thus left him unprepared for life after school. It seems as though Martin has been labelled by societal institutions from a young age, and has had difficulties ever since. His own recognition of his social disadvantage is fully apparent. A third service user, Craig, also draws attention to the limitations of his label:

Extract 4a.3 – "I don't class myself as having this, but the Government states that I have slight learning difficulties. I have a few problems with remembering things some times. I don't want to identify with that label, it used to bother me that people thought I had a difficulty but now I just accept it and I'm quite open about it." (Craig)

Again, the label appears to have been given from an outside agency, which is more powerful than the service user. The implications of this are that unless the service user identifies with having an intellectual disability, then they will automatically come into a research project with some feelings of being an outsider. In these extracts, it seems as though the society around the individual creates and develops the disadvantages that people with intellectual disability perceive. Elizabeth offers her own opinion about labelling:

Extract 4a.4 – "I think if you're gonna do research on someone with learning disabilities then you mustn't label them as a learning disability because I think that upsets people sometimes." (Elizabeth)

In the above quote, Elizabeth appears to be referring to the problems of labelling in the third person. I believe that this gives further evidence that she is refusing to identify with the label. With all of the above quotes it is important to consider the limitations of the sample. It may be reasonable to suggest that people with more severe intellectual disability experience labelling and disadvantage to a greater extent than the relatively able service users who have

presented their views here. I was unable to support this assumption through interviews and quotes due to the communication difficulties which hindered interviews.

#### **4a.2 Getting help**

Bearing in mind the feelings of disadvantage and powerlessness that service users may possess, they may unsurprisingly feel the need for help and support from professionals. Many of the interviews indicate that service users in this particular study needed help and support in order to achieve a better quality of life:

Extract 4a.5 – “Yeah I did want them to help me [...] ’cos I wasn’t really happy with myself” (Lisa)

Extract 4a.6 – “I mean ... for me to go to be where I am today I couldn’t have done it without...community teams, advocates, anything, I wouldn’t be here today...that’s an honest truth.” (Elizabeth)

Extract 4a.7 – “people like myself and other people, they probably you know, would need that extra bit of like *kick*.” (Martin)

These extracts indicate a need for help. Elizabeth indicates a great deal of satisfaction with the services that she has received, even going as far as to imply that she would not have been able to cope without being able to access these services. She mentions that at least two services have been available to her; advocate services and nurses from the community teams. Craig describes his experiences of intellectual disability services in the past:

Extract 4a.8 – “I found it helped a lot with my confidence. It didn’t come overnight, but over a period of time. It started to help then I didn’t feel like I needed it, so I didn’t really...I’ve felt really good. I haven’t felt depressed since I stopped seeing them. I’ve been pretty happy in mood, not that bad.” (Craig)

However, it should be noted that not all people with intellectual disability should be assumed to require support. Craig states that he has not required help and support at all times throughout his life, but that it has been helpful at certain times when he was feeling unwell. He has found external support from an occupational therapist helpful in the past, but he believes that he no longer needs this help and is coping well on his own. At times, the service users espoused more negative or ambivalent views about the services they were receiving:

Extract 4a.9 – “Some of the things I thought ‘what the hell are we doing’...like ‘what are we doing’ and...*why*...type thing.” (Martin)

Nevertheless, when service users felt as though they required help, there were sometimes difficulties in getting that support. On occasions, this was due to the difficulties of accessing the help:

Extract 4a.10 – “they should advertise more, advertise what help is out there [...] they should put posters up, they should put in a leaflet, you can send to everyone’s door. They should be...advertise it on TV, they should...so that people know what is out there.” (Elizabeth)

On other occasions, the difficulties involved in accessing help appeared to have more to do with the resources available in the local area:

Extract 4a.11 – “at the moment I’ve got no community nurse and related to that I don’t know how long I’ve got to wait. So I’ve lost my help, and...you know there’s not, there’s not enough people out there to help. [...] They said they were gonna put me on a course, I’m still waiting. They haven’t got back to me, maybe I should’ve got in touch with them...but they should’ve got resources before they even saw me they should’ve made sure the resources were out there. And, and now I feel that...when professional people *do* that...it then makes you, makes me stronger, for me, to not use them again, to not trust them. It’s really hard for each individual to trust the professionals’ teams when there isn’t enough resources out there.” (Elizabeth)

This kind of disillusionment with services provides an interesting background for anyone who is attempting to conduct an RCT. This is particularly true in the case where the RCT guarantees access to an intervention for 50% of the people who participate, such as the REBUILD study. In the above extract, Elizabeth explicitly makes the connection between disappointment, perceived lack of resources, and her ability to trust people. This quote is particularly illuminating because it shows the psychological pathway by which Elizabeth develops her disillusionment. Her ability to trust professionals is based upon their ability to respond and to deliver services to their word. I think there is a message that repeated empty promises from service providers can damage the confidence that service users may have in the ability of the service. Appropriately enough, the real reason for the service's non-engagement with Elizabeth in this particular case was due to the fact that she had been randomised to the control group.

Within this climate of limited resources, there was a need for service users to be proactive in acquiring the help they needed. Elizabeth provides the following comments:

Extract 4a.12 – “I looked on what’s out there, talking to other people who have been ... under learning disability. Myself, I wouldn’t have known a group called Coast unless I didn’t talk ... to another patient...under learning disability team, I wouldn’t have known anything about them, by chatting to people [...] I’ve had to fight for all my special people, I’ve had to fight really hard, I’ve had to change my GP three times to get the help that I’ve got. So it’s, if the patient is not, like myself can fight for the help that they want, and keep on pressuring...pressuring the professional people to, you know, to get ‘em the help, then basically that person’s not gonna get the help.” (Elizabeth)

In this case, stamina and perseverance appear to be important qualities for service users with mild intellectual disability who wish to access help and support. It may be equally if not more important for the family and paid carers to possess these qualities, as will be discussed in the Sub-chapters 4b and 4c

respectively. It is worth mentioning that the people who took part in the randomised controlled trial were already known to services. This is how they came into contact with the trial in the first instance. This sample is invariably biased to favour the views of ‘fighters’ like Elizabeth who appear to have ensured access to intellectual disability services. It is possible that people with a more passive nature or less stamina may not be as well known to services, and may not therefore be asked to participate in research projects. Furthermore, the problem of labelling and the feeling of isolation may lead people to reject the notion of registering with intellectual disability services in the first place.

### **4a.3 Perceptions of research**

The context described in the aforementioned section provides important information about how research is likely to be appraised. From the findings, the interviewees had a variety of conceptions and opinions about research, but several trends seemed particularly important. Only one of the six service users appeared to be unable to explain what research was on any level:

Extract 4a.13 – “Something that gets you around?” (Mike)

However, this was an exception in this particular sample. All of the other five service users who were interviewed appeared to have some understanding about what research was:

Extract 4a.14 – “Finding out stuff” (Lisa)

Lisa’s description refers to the most basic aim of research. This opinion was essentially echoed by many participants including carers and professionals. However, this comment reveals little about how she conceptualises research. Fiona elaborates a little further:

Extract 4a.15 – “How people feel, things like that, people’s opinions [...] The way people think” (Fiona)



Again, this is an accurate way to perceive the research process. The emphasis is on finding out opinions. This was exactly what I, the interviewer, was doing at the time of this interview with Fiona. In the following extract, Craig provides his comments on what he believes the research process to represent:

Extract 4a.16 – “People taking notes about your details, getting to know what kind of person you are, what you do in your spare time, trying to find out how they can help you.” (Craig)

Immediately noticeable here is that Craig appears to place the focus of research on the participant. This may be due to his experience with research; people asking him questions and finding out about his feelings. He has taken part in the REBILD trial and was asked such questions. As a person with intellectual disability who is in regular contact with services, he may have been subject to such questioning many times. He also relates to his experiences of market research:

Extract 4a.17 – “If I’m out in town and people try to stop me and say ‘we’re doing some research for a charity’ then I’ll make up some excuse and won’t stop. They’re all after your money anyway, so I don’t do it.” (Craig)

It appears though his experiences with market research have made him slightly suspicious about the process. He alludes to the voluntary nature of market research; he knows that he is not forced to take part. At another point during the interview, he summarises his own understanding of research with the following quote:

Extract 4a.18 – “I haven’t really got an understanding of it; I don’t think anyone has ever told me about it. I think it’s pretty straightforward.” (Craig)

In the above extracts it is interesting to compare Craig’s experiences with research with his own understanding of it, as he paradoxically sees it as a straightforward process. His uncertainty may arise from that fact that no-one

has ever explained research to him in a way that he was able to understand. Perhaps the most detailed description of research comes, again, from Elizabeth:

Extract 4a.19 – “I think it’s like when, like you’re interviewing people...that have been through actually life experiences...and they like...got a condition, they would do research on it to see if there is anything else they can do, to actually improve it. Erm yeah I’m all, all for it, really all for it.” (Elizabeth)

Elizabeth also seems to see research in an immediate context relating to people’s problems, which is possibly influenced by the randomised controlled trial she has participated in. This highly individualised concept of research was common amongst service users:

Extract 4a.20 – “I suppose research is information about the individual” (Martin)

However, Elizabeth also provides evidence that she was also viewing research in a more abstract, less direct way:

Extract 4a.21 – “Research is a big...project as I call it...a big project, to me it’s a project of people...on your behalf researching big areas” (Elizabeth)

It appears as though Elizabeth has grasped the concept of research on two distinct scales. She is aware of the process of asking questions about the individual, but she is also aware that this forms part of a larger picture. Craig alludes to a similar belief in the following extract. He shows interest in what happens in research beyond the immediate context:

Extract 4a.22 – “I’d like to know where does this go, what becomes of this when it is completed. I just wondered really.” (Craig)

Overall, research was seen as a positive experience for the service users, despite the suspicions they may have had relating to previous experiences:

Extract 4a.23 – “I think there should be more *researchers*, when i.e. under learning disability or mental health, or behavioural, wherever.”  
(Elizabeth)

#### 4a.4 Communication and understanding

The most commonly cited challenges for research in intellectual disability are communication and understanding. It is worth noting that these problems are widespread for this population and they have implications for many aspects of service users' lives, quite aside from the problems related to research. Martin, a service user, describes some of the problems. He refers to a recent court procedure that he underwent:

Extract 4a.24 – “people with difficulties...and that sort of thing, ‘do you understand’ that they can read, like a second opinion which you know to help you...So you understand what’s going actually going along around you [...] somebody like yourself...you wouldn’t *need* that.” (Martin)

Martin describes how he needed help to understand the court procedure. He contrasts that with his comment that I (the interviewer) would not need similar help to understand the procedure. This passage implies that people with relatively mild intellectual disability such as Martin may require help to understand unusual or complex scenarios, such as research participation.

Service users' opinions on communication and understanding were interesting as they highlighted the individuality of potential communication problems, as Fiona describes:

Extract 4a.25 – “I’ve got a friend who can’t speak very well, she uses her body language. She used to stutter, so she uses her body language.”  
(Fiona)

Fiona outlines a potential solution for her friend who has problems with communication. This is a complication which became evident, in that different

service users appeared to understand different communication methods. Fiona expands upon this:

Extract 4a.26 – “A couple of my friends are Down’s and they can use sign language, they can lip-read as well. There’s two of them, they’re both very good at signs, very good. One of my dancing friends, his mum teaches sign language. It’s not easy to do or understand, I can’t do it. I have deaf friends as well, old friends – I don’t see very much. Some people with learning disabilities can be very good at signs; it depends on how your brain works.” (Fiona)

Fiona emphasises the individuality of communicative ability; she cannot use the same communication techniques as some of her friends. This indicates how people with intellectual disability can develop complex skills in order to account for communication deficits elsewhere, which means that communication with people with intellectual disability will not necessarily follow the conventional lines that researchers may expect. Pictorial information was particularly popular among some service users who were asked how understanding might be improved:

Extract 4a.27 – “Using pictures might help” (Fiona)

Extract 4a.28 – “By showing them pictures” (Mike)

Limitations in understanding and the use of communication aids have implications in asking people with more severe intellectual disability to participate in research. Service users had mixed views regarding communication in relation to participation in research studies. Lisa offers the most straightforward viewpoint:

Extract 4a.29 – “I think you still need to ask for their permission first”  
(Lisa)

This shows the fundamental ethical view that no service user should be taking part in a research study without first giving consent. No matter what their

capacity level appeared to be, the principle is that the researcher needs express permission before enlisting anyone. Another service user described how, in some contexts, it may be acceptable to communicate by proxy through a carer, with sufficient caveats:

Extract 4a.30 – “If they know them, if they've known them from the beginning, before they were a lot worse where they *couldn't* talk for themselves. *Only* if they've known 'em for, since they were kids or babies I think it's fair enough, err but if they don't, if they've only known 'em for a couple of years, no. They shouldn't do it. If they can't do it themselves then they shouldn't get the carers to do it, because then they don't know them.” (Elizabeth)

Elizabeth seems to think that the depth and longevity of the relationship are important factors when determining the validity of proxy permission and assent. This implies that family members are in a better position to provide proxy permission than paid carers because they will have known the service user since they were young. The opinions of family and paid carers on this matter will be discussed in the Sub-chapters 4b and 4c respectively. Another service user offered a much more lenient view on proxy communication, which contrasted strongly with Elizabeth's view:

Extract 4a.31 – “I think everyone's got a right to research [...] the people doing the research would have to make their mind up for them because they couldn't do it themselves.” (Craig)

Craig was a service user with mild intellectual disability, who was able to provide informed consent for the trial. Craig appears to suggest researchers should make proxy decisions to enlist people who lack capacity into the research study. This view was not found anywhere else within any of the interviews. Still, the point I think he is making here is that even people with very severe intellectual disability have the right to participate in research, and that this right should not be forsaken because of a service user's difficulty in communicating their individual preferences.

#### 4a.5 Perceptions of the trial

Difficulties in communicating and understanding were pivotal to service users' engagement with the RCT. Of the six service users who were interviewed, all of them found the process difficult to comprehend. Perhaps unsurprisingly, the word 'random' was not well understood. The following extracts demonstrate this, when asked to define it:

Extract 4a.32 – "I suppose you're asking in a roundabout way...a question" (Martin)

Extract 4a.33 – "Looking around?" (Mike)

Martin appears to have confused 'random' with 'round', and it seems as though he is trying to find a context specific meaning for the word, based upon what he has understood about the research. Mike appears to have confused it with 'around'. In both instances, this shows that any usage of the word 'random' is likely to confuse participants with intellectual disability, as it may be an unknown word. Another service user, Craig was equally unsure about what it meant:

Extract 4a.34 – "'Random' means basic like...'random' means...it means basic stuff what goes on, like pretty basic" (Craig)

Craig does not appear to understand the word at all. This shows that even the most capable of service users (this participant held a full-time job and lived independently), will have difficulty understanding terminology that researchers and clinicians may use.

The word 'trial' was slightly better understood. It was seen by some service users as a way to test by literally 'trying things out' before being implemented in a more comprehensive fashion. The following extracts from service users show this:

Extract 4a.35 – "You try something for a while and see how you get on" (Lisa)

Extract 4a.36 – "Like on a trial basis, [for] people who come for jobs"  
(Mike)

This lay conception of a 'trial' is consistent to some extent with the scientific meaning of the word. The RCT is conducted to test the effectiveness of a particular intervention or treatment, which may only be available on a trial basis. If the results of the trial are positive, then the intervention or treatment may be used on a longer term basis, on a larger scale.

There was little evidence to suggest that any of the service users interviewed had a full understanding of the RCT. However, Craig demonstrates that he has understood the basic rationale behind the trial, to test the effectiveness of the service:

Extract 4a.37 – "Just to see how well the service is run from a scale of one to ten" (Craig)

This extract suggests that Craig understands that the trial is focused on investigating the service, rather than investigating him. In turn, this suggests that he has avoided the therapeutic misconception in this instance. Similarly, there is evidence to suggest that Fiona may have understood the methodological concept of blindness in research studies:

Extract 4a.38 – "If some pulled out of a hat, *you* wouldn't know would you?" (Fiona)

Her response was prompted by an analogy of pulling names out of a hat in order to assign participants to intervention and control groups. She appears to be relating to the idea of maintaining the blindness of the researcher. She does not elaborate upon why she believes this to be beneficial for the research, but it is possible that she is referring to the need to reduce human influence in the research procedure.

Overall though, it would be a mistake to assume a sufficient level of understanding of complex RCT concepts for the service users that were

interviewed. For example, Martin finds it difficult to explain how my role as researcher fits into his service provision:

Extract 4a.39 – “I didn’t know now, I don’t still don’t know what you are, what your involvement is.” (Martin)

Martin suggests that he has not understood the role of the researcher over the course of the trial. Of course, if misunderstanding is encountered at this stage, then the reasons behind the randomisation procedure are likely to remain a mystery. The following extract demonstrates this, as Martin is trying to explain the reason why participants were allocated to two groups from a vignette:

Extract 4a.40 – “they can’t *all* go and see the same person so she’ll get the same answer, so they have to separate ten people from the other persons, with one lot to one person and one to another, and work with them.” (Martin)

Martin attempts to explain why some participants were allocated to an intervention group and other participants were allocated to a control group. This passage indicates his confusion, and he does not appear to have understood the procedure. Fiona admits that she too finds it hard to understand:

Extract 4a.41 – “It’s difficult to understand, another way would be better, because the patients would find it easier.” (Fiona)

Fiona emphasises that service users may have difficulty understanding the procedures of an RCT, and thus she suggests that she would prefer a simpler procedure. Finally, Elizabeth appears to assume that the randomisation procedure is linked to the provision of resources for people with intellectual disability:

Extract 4a.42 – “I think it’s because there isn’t enough nurses out there...there isn’t enough nurses, there isn’t enough...help groups, there isn’t...to manage, there’s a lot of patients out there that need help.” (Elizabeth)



In Elizabeth's paradigm, service users were allocated to two different groups because resources were limited and there was not enough capacity to include every service user in the intervention group. This was the only time a service user suggested this, although this viewpoint is comparable with the views of many of the carer and professional interviewees, whose comments shall be presented in the following sub-chapters.

Upon presentation of the trial vignette for service users, some were able to reflect upon the ethics behind allocating participants through random selection. Lisa describes how she feels about random allocation through use of a computer:

Extract 4a.43 – "I don't think it should be chosen by a computer I think people should actually go through more...who needs the help the most and then put them at the top. [...] I think everyone should really get the help, I don't think you know, otherwise it isn't fair." (Lisa)

As opposed to randomisation, Lisa would appear to prefer a system based upon prioritising the needs of an individual. This belief reflects the views of several carer participants. She appears to suggest that random allocation has implications for fairness to participants. In wider practice within health and social care services, prioritisation would be easy to implement and may reflect normal practices. However, this system would be unworkable within the context of an RCT because it would introduce systematic bias to the results and therefore conflict with the theoretical basis for randomisation. The following extract from Craig appears to show a similar viewpoint:

Extract 4a.44 – "it really depends on if they see one party before the other, because it could be unfair to do the other people if they didn't get that treatment. That's just my opinion. I think everyone has got the right to equal opportunities, and the right to express themselves and get services." (Craig)

Extract 4a.45 – "six months is too long to wait for help. Within that time, those other ten that didn't get the help six months before were now

probably...in and out of hospital, lost, don't know where they're going."  
(Elizabeth)

Craig appears to refer to the concept of fairness in relation to equal opportunity to access services. The importance of service access is paramount. Randomisation may be perceived as unfair because participants receive differential intervention at a particular point in time. Elizabeth shows anxiety regarding the six month latency period for receiving services, as experienced by participants who were allocated to the control group. Nevertheless, one service user showed that she was not taking the effectiveness of the resource for granted:

Extract 4a.46 – "I've not been doing it very long, so I don't know, only been two or three times. I think I will find out whether they are helpful after a bit longer." (Fiona)

Fiona is answering a question about the helpfulness of intervention. She suggests no inherent value without seeing the outcomes for herself, and therefore she appears not to hold assumptions about the intervention's effectiveness.

#### **4a.6 Motivation to participate**

It was also interesting to discuss the service users' motivation to participate in the trial. Surprisingly, considering the fact that the trial was not well understood, service users did hold some understanding about why the trial was conducted:

Extract 4a.47 – "The student has been helped [and] The services [and] The people that work there, of course" (Fiona)

Fiona is answering a question based upon a vignette, about who would potentially stand to gain from the trial. She astutely recognises that the researcher and the service being investigated may potentially benefit. This

refutes the claim that service users are purely relating to the trial on an individualistic basis. Lisa corroborates this:

Extract 4a.48 – “I think it will help people like me...later probably” (Lisa)

Here there is recognition that the trial may have further reaching implications than purely the individual participating. These service users appear aware of the potential wider gains from the research. In keeping with this theme, Elizabeth appears to show both altruistic and self-interested motives for taking part:

Extract 4a.49 – “I think it’s good because you get input off everyone else who...you have input in the fact that you can get your point across...to the researcher, then they can do the research on any information at the end of it, it’s really quite a good input. You feel like you’re giving something to the researcher...I think it’s good input.” (Elizabeth)

Elizabeth describes the process of research participation. She feels that research has been helpful to her and has allowed her to express herself. However, she also believes that she has been altruistic in helping the researcher achieve their own goals.

#### **4a.7 Summary**

The study was hampered by a limited sample of service users with mild intellectual disability who could be interviewed. Of those that were interviewed, two were randomised to the REBILD control group, and the other four were randomised to the intervention group. The service users that were interviewed did appear to have some understanding of the basic concepts of the trial. They found it easier to relate to concrete examples when answering the questions, at times these were related to research and at other times they were related to other areas of the service user’s life. They were mainly positive about the research process as far as they understood it, though there was no evidence to suggest that any of the service users fully understood the RCT. Procedures such as randomisation and comparison groups appeared to present difficulties

even after being shown a vignette of the trial situation. The views of service users regarding access to the intervention can be compared to the views of family carers, who will be discussed in Sub-chapter 4b.

## **4b. FAMILY CARERS**

Sub-chapter 4a has described the results from the interviews with service users. Many of the themes presented therein were also described by family carers in Sub-chapter 4b, although there were also differences in the way family carers and service users understood the trial. All of the family carers who were interviewed were mothers of people with intellectual disability who had taken part in the REBILD trial.

### **4b.1 Views about the intellectual disability context**

Family carers represent a distinct group of stakeholders in this study. In many ways they shared concerns with paid carers and with service users. Like these two groups, they were keen to highlight the differences amongst individuals with intellectual disability. This could affect their beliefs about how research was conducted:

Extract 4b.1 – “it is difficult with people with learning difficulties because there’s such a wide spectrum of different things...that people have [...] sometimes there’s not an a ‘yes’ or a ‘no’ to any questions, sometimes it’s a ‘yes sometimes but’ then other times you know, something totally different.” (Sandra)

This spectrum of different issues could be seen to create an extra layer of individuality, based upon the nuances of having an intellectual disability, as Theresa also insinuates in the following extract:

Extract 4b.2 – “I’ll tell you something it’s because special needs behaviour and things is so diverse that you’ve got to really cater it to how a person will react, how they will respond, and whether they are capable of speaking, whether all their disabilities have actually got to be taken into account.” (Theresa)

Theresa notes the importance of complexity in this population, especially with people with challenging behaviour. She refers to the importance of accounting for the full range of an individual's disability. I believe that this refers to co-morbid disability that the person with intellectual disability may have. This seems to make it harder to help people. Parents appeared to consider the uniqueness of their child when searching for help and support:

Extract 4b.3 – “I would say the main support network is other parents...but you go to other parents and they probably haven't had the same problems.” (Anna)

This extract shows a mechanism by which Anna has sought support for a problem involving her son. It is crucial to remember that family carers' point of reference for the RCT was the fact that they were seeking help for a problem with their son or daughters' behaviour. It is necessary to remind the reader that this qualitative investigation was based around a sample of service users who had been referred to a specialist behaviour therapy intervention for help with challenging behaviour. Their challenging behaviour may have involved verbal and physical aggression, destruction of the environment and various types of self injury. Therefore, the need for help may have been severe in some cases. This perception of the problems is illustrated with the following quote from Trudy, who is talking about her daughter:

Extract 4b.4 – “I wasn't able to handle her, I was getting to my wits' end so to speak really about X and that's why I thought I've got to have extra...get some professional help, I knew that she needed professional help.” (Trudy)

Extract 4b.5 – “there was great difficulty in getting her to walk about and she was very aggressive and all that sort of thing.” (Elsie)

These family carers are talking from the perspective of needing help. Interestingly, Trudy's extract reveals her perception that both she and her daughter needed professional help. I interpret her comments as though she has exhausted her own coping strategies and is beginning to seek support from

outside. Anna takes this one step further in the following extract, which describes her son's behavioural problems. She indicates how her son could cause problems in wider society:

Extract 4b.6 – “I'm not just saying we as a family I'm saying you know society and everyone to deal with X, you know that sounds a bit cruel really saying 'to deal' with him but to deal with his behaviours, to find strategies and ways of coping with him and because it's not just X that needs to cope with it, it's the carers and everyone else needs to *cope* with it as well.” (Anna)

Both Trudy and Anna lived at home with their child at the time when the RCT was taking place. In the case of Anna, her son moved out of the family home during the course of the trial. He moved into a residential care home in a neighbouring county. However, not all family carers espoused such drastic views:

Extract 4b.7 – “she's just like a toddler really, and she can be brought down, and she can give in a bit.” (Jean)

Jean's daughter was also living with her in the family home. I interpret Jean's words to signify that she herself does not necessarily have a problem with her daughter's behaviour; she knows how to control the behaviour and she does not believe that her daughter means any harm by her actions. However, she expands upon this in the following extract, which refers to a problem situation occurring at the day centre attended by her daughter:

Extract 4b.8 – “she had a few behavioural problems, she pushed a couple of girls over...so social services and...the community nurse stepped in and...they thought she was some sort of criminal really but yeah, they thought behavioural people should come in, she has got some other behavioural difficulties as well.” (Jean)

In the above passage, Jean states that her daughter does indeed have behavioural problems. However, she implies that there is a discrepancy

between how these problems are appraised by herself and by other members of the community. She suggests that health professionals have misunderstood her daughter's actions to a certain extent. Furthermore, the mention of health and social services shows how wider networks of stakeholders are introduced into the lives of people with intellectual disability. The following extract reveals further input:

Extract 4b.9 – “We have from the adult...side we've had a behavioural therapist and we've had two meetings, the therapist is actually working more with the day centre really [...] Well she goes into the day centre to give them advice, and then there's a meeting and we all go into a meeting after that.” (Jean)

This extract clearly shows how the behaviour therapy service has begun to provide input with this participant. This shows how the RCT itself has allowed for the provision of resources. Interestingly, the extracts from Jean appear to show her mixed feelings about the nature of some of this input. She feels as though the services are 'stepping in'. Jean may feel that others are misunderstanding her daughter, or overstating the severity of her daughter's problems. She feels that others have labelled her daughter as 'some sort of criminal', which relates to the theme of labelling as discussed by many of the service users in the Sub-chapter 4a. Jean's comments suggest the presence of labelling in people with intellectual disability, and that labelling may affect how people are seen by society. Trudy illustrates her and her daughter's experiences with societal labelling in the following extract:

Extract 4b.10 – “Sometimes I feel...that the way people look...at her for instance, I feel they look at her and they think perhaps she's 'ooh she's perhaps some kind of monster' but...she isn't a monster she's a very sick girl that needs a lot of help and a lot of support.” (Trudy)

Trudy's use of the phrases 'monster' and 'very sick girl' are immediately striking in this passage. I interpret this as a mixture of two experiences of how society reacts to her daughter; rejection and fear. The concept of fear only arose in a



small percentage of the interviews and was not a major theme. Anna makes some alternative suggestions on the theme of labelling:

Extract 4b.11 – “why have we still got all this you know, erm not antagonism what’s the word I’m looking for? *Bias* against disabilities and jealousy to a certain extent isn’t it [...] Yeah you know jealous that your disabled I mean that’s, you know that is to me is ridiculous [...] and labelling and things like that.” (Anna)

I find Anna’s use of the word ‘jealousy’ interesting. This is the only time this theme arose in any of the interviews. I am unsure about how to interpret it but it appears to be related to the larger concept of discrimination. This seems to be a problem that is obvious to parents of people who have intellectual disability, particularly in this study where the service users displayed challenging behaviour.

#### **4b.2 Funding and resources**

The feeling of desperation and disadvantage became important when thinking about how funding and resources were distributed within the intellectual disability community.

Extract 4b.12 – “Well, they’ve never got the money, you want something, you need something ‘we haven’t got the money’” (Jean)

Extract 4b.13 – “resources are quite hard” (Sandra)

In the following extract, Theresa shows her feelings about how people with intellectual disability are seen as being near the bottom of this list of priorities for society:

Extract 4b.14 – “if the Government hasn’t got the money or its short of money I’m afraid the first thing they look at is, seems to *be* the disabled, the mentally unstable, learning difficulties” (Theresa)

The problem of obtaining funding for services for people with intellectual disability was an important topic for service users, carers and professionals alike. For family carers, there was often a strong sense of feeling let down by professionals in the past:

Extract 4b.15 – “we’ve had a lot of things promised in the past and things haven’t appeared or we’ve been told ‘sorry there’s a lack of money so this won’t be happening’ [...] she was supposed to go on several courses to help her and they never came so...we weren’t even told that she wasn’t gonna get them until we’d gone back to the doctors and we were told that ‘well you’re gonna be very lucky because of lack of money’. Erm, and in the *end* when you come up against so many brick walls you do tend to stop trying [...] you feel very disheartened and you sometimes do feel very isolated.” (Theresa)

Theresa’s comments evoke a feeling of resignation with regard to previous experiences and empty promises. This feeling is based upon a perceived lack of financial resources in intellectual disability. This extract indicates that as a parent, Theresa has had trouble forming links with professionals. She again relates to her problems in finding adequate resources for her daughter, and has experienced disappointment in her interactions with professional services. This appears to have bred a sense of isolation and uncertainty, which has decreased her satisfaction with services. Similar comments are echoed by Anna, another parent:

Extract 4b.16 – “we are always being told ‘you can’t have this ‘cos of funding, you can’t have that ‘cos of funding’ etc, etc so we’re always unsure...learning disabilities there’s nothing ever *sure*, there’s nothing ever concrete but I’m not saying that that’s you know any different in any other mode of life” (Anna)

Anna’s comments indicate a certain amount of powerlessness and uncertainty with her situation. However, parents were not always too critical of the individuals within the services themselves. For example, Anna also comments about the usefulness of services when they have been available in the past:

Extract 4b.17 – “there wasn’t much of a team until he became 16 [...] and I just couldn’t believe it people were knocking on my *door* to talk to me about X, whereas before that the first 16 years...I was screaming on the phone and going berserk and trying to get people, just to show some kind of interest. [...] when he became 16, we were all were walking round with a smile on our face.” (Anna)

Anna’s comments are interesting because they show how uneven her experience with service provision has been. She has been trying to get services for her son ever since he was born, but it was only when he reached the age of 16 that she received any services. She could not understand why this was the case, but her comments indicate that this newfound access to services had positive consequences.

There was often a feeling that service providers had good intentions and provided useful support. However, this was contrasted with a perception that the Government was controlling and limiting access to financial resources:

Extract 4b.18 – “They *want* to give you the things that you *need*... *but*...they know that there is these things available, however it’s, I think it’s down to Government funding.” (Theresa)

Extract 4b.19 – “I feel if the Government were able to perhaps give a bit more funding...people would get a lot more help and support.” (Trudy)

The good intentions and positive impact of local intellectual disability services appear to be somewhat undermined by a perceived lack of financial support from the Government. Trudy seems to be blaming the Government for not providing enough funding, but the concept of ‘Government’ in these extracts appears to be abstract and detached, suggesting that family carers tend to feel especially removed from financial decisions regarding people with intellectual disability.

This context of limited resources ensures that help seeking behaviour amongst potentially isolated families is an active process. In short, intellectual disability

services may not be widely known to the family carers that may need to access them:

Extract 4b.20 – “you have to find out yourself or someone has to find out for you because it’s not widely *advertised* all these other different groups and whatever things that you can *find* help, some people don’t think they’ve got any help at all.” (Patricia)

Patricia refers to a group of people that will not receive any help from professional services because they are simply not aware of them, and lack the networks to be able to find out. This is perhaps the key difference between paid carers and family carers, and it somewhat aligns the views of family carers with those of service users previously discussed. Active persistence appears to be the key to accessing help:

Extract 4b.21 – “it takes stamina to fight for their child or the person that they’re caring for [...] if you don’t ask you don’t get and even when you ask, you still have to, you have to become a *pain*, and in a lot of areas we’ve had to become a nuisance.” (Theresa)

Extract 4b.22 – “you have to fight, you have to fight for the services.” (Jean)

These extracts show a belief that the services will offer no help unless they are pressurised. This relates back to the perception of inconsistent funding for services for people with intellectual disability. She feels the need to fight for her daughter in order to achieve a positive outcome.

### **4b.3 Perceptions of research**

Like other stakeholders, family carers were positive about research, and they showed a preference for purposeful, targeted research. Unsurprisingly, they seemed to place a great emphasis on the practical research outcome, as summarised in the following extract:

Extract 4b.23 – “I think it’s a good idea, it depends if it’s just research or if they’re actually gonna do something with it” (Jean)

The application of research was seen as essential. In describing a research process below, Anna describes how research can be used to provide a more independent valuation of a service:

Extract 4b.24 – “people and services can go along and all you’re led by is your manager, and if your manger gets a bit staid or things you know, it just stays stale, if you’ve got it being assessed then you can find out whether it *is* worthwhile, what *isn’t* worthwhile, what *is* and how to improve the service, because your never gonna improve anything unless you have assessment on it or research into it.” (Anna)

Anna seems to suggest that external service monitoring provides a basis from which services can be improved. She seems to relate to this as a primary function of service-based research, in fact she may believe that research is the only way to improve the service. Therefore, research was seen as a beneficial process if it was applied and useful. There also needed to be a feedback mechanism to ensure that family carers were not being isolated from research outcomes:

Extract 4b.25 – “it would be nicer to sort of, so that that you *knew* exactly the end result, what was actually going on with the research, I mean you’re told obviously that certain things, but it would be nice for people to know the *whole* picture rather than just the bits that they *need* to know.” (Theresa)

This shows that Theresa’s curiosity about the workings of the research process, and her interest in the outcomes. She also appears to believe that there are issues of transparency in research, such as freedom of information. This relates to the fact that the outcomes of research may not always be disseminated as widely as the family carers would like.

Overall, there was a feeling that research was good because it had the potential to initiate change within services. In the following quote, Patricia implies a belief that past research is responsible for the current state, just as current research is necessary to make improvements for the future:

Extract 4b.26 – “if we didn’t have research we wouldn’t be where we were today would we? [...] if research wasn’t done the scientists and things didn’t do what they’ve gotta do we’d never...go out...you know get further on in medicine and whatever.” (Patricia)

From these interviewees’ comments it did not appear as though family carers were against the idea of research to assess a service, as long as it was done for productive and purposeful reasons. Anna corroborates this:

Extract 4b.27 – “there is so much missing for learning disability people in general but I *don’t* think...I mean no-one minds kinda quote ‘being a guinea pig’ we don’t worry about that at all, that’s not a problem to us.” (Anna)

Whilst Anna does not overtly express altruistic motives, she makes a statement about the social disadvantage encountered by people with intellectual disability, and she demonstrates her willingness to participate an RCT within this context. For Jean however, the reason for participating appeared to be more simple:

Extract 4b.28 – “I didn’t think I had anything to lose” (Jean)

Although the family carers in this study appeared to be accommodating towards participating in the RCT, they often appeared far less accommodating when asked to discuss drug research for people with intellectual disability:

Extract 4b.29 – “if it had been a new drug trial I wouldn’t have done that, no. I wouldn’t have even gone for it; he’s got enough problems in life without going like something like that because you know, side effects anything.” (Anna)

Extract 4b.30 – “a drug can have side effects, a service don’t usually have side effects.” (Jean)

The problem of side effects appeared to be important, since family carers in this study were most likely accustomed to trying new medication for their son or daughters’ challenging behaviour. Family carers were concerned about the potential harmful effects of drug research:

Extract 4b.31 – “It *can* be harmful if it doesn’t go right for people with learning disabilities but...as I say, if you’re trying out a new drug that can be potentially very, very dangerous. We all saw what happened recently, didn’t we? In the hospital?” (Sandra)

Sandra makes reference to a recent clinical trial which had been reported in the media several months before these interviews were conducted. This trial was a national scandal because several participants had been grievously affected by the side effects of the medication. Others corroborated this view:

Extract 4b.32 – “we’ve recently had something on the television where we’ve had these people that have gone in for a drug and at least two or three of them, they’ve been told that they could get cancer later on, and from one person who’s been through it you [laughs] that is absolutely *despicable*, its deplorable and it should never have been allowed to happen.” (Theresa)

Extract 4b.33 – “I don’t know I mean look what happened when they tested those drugs on those people...a while ago. You know it had disastrous effects and you just wonder how far you can go without it all going pear-shaped? Obviously there’s gotta be medical research hasn’t there? But where it begins and ends I don’t know.” (Elsie)

Therefore, parental views on research appeared positive but at the same time they were likely to be vehement if there was any chance of the research causing complications for the service user. This highlighted another dilemma of

getting consent for research. Theresa offers her opinion on gaining consent by proxy:

Extract 4b.34 – “I wouldn’t just go by the carer and parent because again it’s a very, very sticky and a very awkward situation. I think you’ve gotta have an input from everybody, psychiatrists, doctors, consultants *but* I do feel the perhaps 60-70% of the results should come through the carers.”  
(Theresa)

Theresa suggests that approaches involving a limited number of stakeholders may not be appropriate. Interestingly, she downplays the involvement of parents and carers, suggesting that professionals should be involved in consent decisions. Of course, it is also noteworthy that she weights the consensus decision process significantly towards the carers. In another case, Elsie appears to be far more relaxed about the consent process for the research:

Extract 4b.35 – “I don’t think she knows anything about it anyway. You know, she seems quite oblivious to what’s going on, you know...I’ve been OK with it.” (Elsie)

As a parent who has made a proxy decision to participate in the trial, Anna has a slightly different view:

Extract 4b.36 – “*we are and were* his consent on this, but we knew that it was for his good, and that why we at the...but whether it was the behaviour therapy, whether it was the community learning, that meant *no* difference to X...himself, it wouldn’t have mattered whether it was the Pope.” (Anna)

Anna describes the process of providing permission for her son to take part in the randomised controlled trial. She justifies her approach on the basis that she felt that it was for his good, and that her son would be oblivious of the research process, and to any interventions that may result from taking part.



#### 4b.4 Perceptions of the trial

Whilst it is accurate to suggest that family carer participants had a ‘working’ knowledge of the purpose of research, the purpose for random assignment to different allocation groups in an RCT was more difficult to grasp:

Extract 4b.37 – “It seems very, as you say, very *random* to pick them by computer as to say one...Group 1 or Group 2. I don’t quite see the point of it.” (Elsie)

For this participant, ‘random’ seems to illustrate a lack of purpose. For her, the participants have been randomly assigned to each of the two allocation groups, but she does not understand why this has happened. Some other participants seemed to be very confused by the use of the word:

Extract 4b.38 – “I don’t really know what that...means” (Trudy)

However, some of the interviewees appeared to be more knowledgeable about the purpose of the RCTs, as illustrated in the following quote:

Extract 4b.39 – “Because otherwise what have you got to compare it with? You’ve got no comparison. If everyone gets the same...service, if everyone got say both, if everyone just got the behaviour therapy service, then what have you got to compare it against? You’ve got nothing.” (Anna)

This extract shows how Anna has understood one of the fundamental concepts of the clinical trial; the need for a comparison group in order to ascertain the effectiveness of the behaviour therapy service. Interestingly, Anna and her son were randomised to the intervention group:

Extract 4b.40 – “when their number came up when we were sort of you know taken out of the computer and we thought *yeeahhhss!* this is it now we’re gonna get this [...] I’m probably more biased because we were given [laughs] we came out, the number, you know our number came up and so we got the behaviour therapy service. If we *hadn’t* have done or

we'd have had to wait a lot longer...then I don't know whether I'd be saying it was fair. I don't think I probably would've been. I think I would've been a bit more grumpy about things, yeah." (Anna)

Anna describes how the random allocation fulfilled her preferences and allowed her to access resources more quickly for her son. She admits that this has shaped her opinions about the process. By the same token, not understanding the nature of this process could cause confusion for other family carers:

Extract 4b.41 – "I still couldn't understand why nobody was involved with her when I felt that there should be somebody *involved* to help me to...tell me how...if I'm handling things wrong with her, and to give *me* a little bit of advice [...] I didn't understand what it meant, I thought that once [the nurse] had put her information over to them that they would automatically get involved with X...and it didn't work out that way in the end." (Trudy)

This extract shows the problems that can occur if the family carer has misunderstood the procedure of the trial. Here, Trudy is clearly confused about the process. She has sought help and advice from a service but has been left without help. If misunderstanding is encountered at this stage, then the reasons behind the randomisation procedure are likely to remain a mystery:

Extract 4b.42 – "I don't really know, I don't understand. Why do they have two groups? I mean why are they not all assessed the same?" (Elsie)

Perhaps unsurprisingly, several interviewees related this to both the rationale behind the research and to the reason behind random allocation procedures. The following extracts highlight the simplest relationship between these factors:

Extract 4b.43 – "Probably because there's not enough room to get everybody *in*" (Sandra)

It is important to remember that provision for services for people with intellectual disability is not seen as sufficient to meet requirements. Therefore, randomisation can be seen as a way of limiting access to services for participants, a type of rationing procedure. This is true to a certain extent within the context of REBILD; the randomisation procedure replaced a waiting list procedure. Therefore, the intervention service was believed to have insufficient capacity to provide input to all of the participants, or even to provide service users with a more comprehensive assessment procedure in order to prioritise need:

Extract 4b.44 – “it’s a cheaper method of doing it and again we’re down to money. ...Whereas if we’ve got people coming to visit...carers and people with problems it’s costing more money because it’s costing their wages, a computer you plug it in, feed the information in and Bob’s your uncle.” (Theresa)

Theresa suggests that randomly allocating participants to different groups is cheaper than allocating services based upon prioritisation, since the latter would require a needs-assessment exercise. For Sandra in the following extract, randomisation is a fair procedure because it affords equal opportunity to receive a service:

Extract 4b.45 – “It’s fair because everybody should have an equal opportunity, everybody should get an equal opportunity to be able to take advantage of the service” (Sandra)

For all of these family carers, the ideas behind randomisation are inescapably linked to resource provision. Randomisation both allows and denies access to services which are being tested, and therefore it can be seen positively and negatively depending on the outcome for the participant and family.

#### **4b.5 Summary**

The family carers interviewed in this study appeared to be highly sensitive to the individual needs of their son or daughter. They were keen to show the complexity of the problems they were facing and thus it was important for them

to be able to provide an accurate picture of their situation to the researcher. Several of these interviewees described their feelings of isolation, including from professional services. Multiple experiences of inadequate service provision may lead to family carers becoming disillusioned with services or feeling as though the services are under-resourced and under-funded. These family carers appeared to have a variable understanding of the principles behind randomisation, and were naturally more concerned with finding access to services in order to help their son or daughter. If the trial would preclude access to a resource or intervention that would potentially aid their struggle, then they would be likely to view the trial in a positive light. There were difficulties however with some family carers who did not appear to have understood the likelihood of being randomised to a control group, which seemed to cause confusion. Sub-chapter 4c will discuss the opinions of paid carers, whom there are marked similarities and differences to the family carers.

## 4c. PAID CARERS

The previous sub-chapter has described the finds from family carers, which in turn has built upon the findings from service users. Sub-chapter 4c will attempt to describe the paid carers' views. Paid carers are defined as those stakeholders who provide regular paid care for an individual with an intellectual disability. This group includes residential carers and their managers, inpatient unit workers, and those who provide day care through day services. All of the paid carers who were interviewed had acted to help a service user take part in the REBILD trial.

### 4c.1 Views about the intellectual disability context

Among family carers and service users the theme of labelling was apparent. Paid carers referred to labelling differently. Most of these people had experience of working with a large number of individuals with intellectual disability, and they often made allusions to the differences between individuals:

Extract 4c.1 – “people with learning disabilities are so *different* that each and every one represents himself individually” (Thomas, paid carer)

Of all the stakeholders, paid carers probably have the largest number of close relationships with service users. Paid carers may work in a residence with up to a dozen service users, and provide intimate care for several of the residents. This may relate to the sceptical views that some paid carers had about the quantitative surveys that they were being asked when they participated in the RCT:

Extract 4c.2 – “I don't know if it's so easy to...quantify the behavioural programs, even when just taking the people randomly it seems...people with learning disabilities are so *different* that each and every one represents himself individually [...] You have to be very careful with this

research before you make a statement about the service.” (Thomas, paid carer)

Thomas alludes to the problem of quantifying outcomes for interventions for people with intellectual disability. He discusses the individuality of people with intellectual disability, which he seems to see as a factor that complicates quantitative research with this population. He warns that caution is required before making generalisations based upon quantified data. Similar scepticism was found elsewhere with regard to the questionnaires and to the trial:

Extract 4c.3 – “I can see the relevance and I know why you’re doing it but you know when you used to come with all those questions and you’d, yeah and you’d ask a question and my head would be spinning because you can’t just say ‘yes’ or ‘no’. It’s not...life’s not black and white, people aren’t black and white and we’re all shades of grey, and people with a learning disability have got a zillion shades of grey. *How* do you do that in boxes?” (Sue, residential care manager)

Like Thomas, Sue suggests that there are problems in accounting for the complex outcomes for people with intellectual disability. She suggests that the individuality of the disability adds complexity to an individual’s character. It is possible that these beliefs underpin the difficulty that many carers had with quantitative measures:

Extract 4c.4 – “a tick-box isn’t always just enough you need to be able to make a comment as well.” (Beatrice, day services manager)

Extract 4c.5 – “as I say the questionnaires they’re very good but they’re questionnaires and questionnaires are never, never accurate because you can only say ‘yes’, ‘no’, ‘maybe’, ‘sometimes’.” (Emily, paid carer)

These comments illustrate feelings about the limitations of quantitative outcome measures, as used in an RCT. The quantitative approach could be seen to lack the depth required to account for the complexity of the research problem in this

population. This may also reflect a desire for carers to be properly understood, and to have their stories heard.

Paid carers therefore often represent an experienced front line of stakeholders who have worked with several service users. Furthermore, they may have worked in other residential homes previously and therefore have a large amount of expertise with people with intellectual disability. Also evident from the interviews was that paid carers tended to have a broader picture of services available for people with intellectual disability than did family carers or service users:

Extract 4c.6 – “I mean when I worked in Leicester we linked in very closely with the Frith Hospital which is very close by, we didn’t have the learning disabilities nurses we just used to ring straight through to the assessment ward and someone would come out from there so it worked differently there” (Tracey, residential care manager)

Tracey describes a different process to the one that seems to take place within this geographical area. This shows how a person working in a residential home is likely to be well linked into local intellectual disability services. This knowledge may also predict a certain disenfranchisement with services:

Extract 4c.7 – “I think they assume quite rightly that people with learning disabilities won’t complain...and that’s why they’re down the ladder if...you know, for services and facilities [...] This borough used to be very good with day services but...now it’s *all* in the community, but access in the community is denied” (Helen, residential care manager)

Helen describes the problem of limited financial resources, which is a familiar story to the family carers described in the Sub-chapter 4b. She refers to a ‘ladder’, which I have interpreted as being a list of priorities for accessing services. I interpret Helen’s comments to express disillusionment with the inefficiency of service provision. Her comments indicate that day services have been repatriated and have become difficult for service users to access.

However, her exact sentiments are unclear. Emily makes her views more explicit:

Extract 4c.8 – “Social services, because they’re the ones who are having to hire these people and fire these people if you like, but they’re the ones that really don’t want to spend out on these people.” (Emily, paid carer)

Emily perceives that social services actively want to avoid spending money on people with intellectual disability. This indicates a conflict between carers of people with intellectual disability and agencies within social services that are responsible for providing funding. People with intellectual disability are seen as being near the bottom of this list of priorities, including for research activity. These views parallel those expressed by service users and family carers regarding the disadvantage of people with intellectual disability in society.

#### **4c.2 The work environment**

Like the family carers described in Sub-chapter 4b, the paid carers who were interviewed in this study had all sought help and support to for a service user who was displaying challenging behaviour within their environment:

Extract 4c.9 – “Umm yeah, he had just moved in to...the home with his behaviours escalating we thought it was best to get the support.” (Lucy, residential care manager)

Extract 4c.10 – “I would have *wanted* X to be selected because I really needed help at that time, and for that actual *behaviour* that X was exhibiting I should say you know, it was *desperate* it was so desperate...I mean, oh God...” (Miranda, residential care manager)

In particular, Miranda refers to her desperation in seeking help for a service user. She wants to receive help for a problematic situation, and she also indicates her own inability to solve these problems with the resources immediately available to her. She shows a clear preference to be allocated to



the intervention group as opposed to the control group. In all cases, the carers had direct experience of these behaviours, often within the context of everyday life:

Extract 4c.11 – “why should staff take a lot of abuse and lots of other things which clients exhibit from challenging behaviour or other inappropriate behaviours?” (Miranda, residential care manager)

These comments indicate that being a professional carer is a difficult job. Abuse from the more challenging service users appears to be common, and Miranda refers to her own right not to be treated in that way. This would presumably affect staff morale and motivation, and may cause problems in working as a team. In the following extract, Miranda explains how she is torn between her duties to seek support for members of staff, and her duties to seek support for the service user themselves. She explains this quandary more fully here:

Extract 4c.12 – “it should be the client who benefits from it because at the end of the day it’s about the client whether staff can deal with it or not, but what the staff are looking at is how to *help* the client deal with his emotional, his behaviour and what not so that, and work in the best interest and in partnership with the client actually.” (Miranda, residential care manager)

This extract indicates that Miranda believes that helping and supporting the staff is secondary to helping and supporting the service user. She seems to be saying that support for the staff can then cascade and help the service user. I think the important point is that the staff and the service user have a closely linked relationship. Providing help and support for one person should result in helping and supporting the other, and these processes should create a feedback loop. Similarly, the team of paid carers need to feed this back into the team. A unified approach to helping particular individuals could be beneficial:

Extract 4c.13 – “There’s no good just one person doing their part ... you’ve got to have everybody involved ... who is involved with the client

with the learning disability, we've got to be working the same, otherwise what's the point?" (Beatrice, day services manager)

Beatrice demonstrates the importance of teamwork from the perspective of someone who works in a day centre. She highlights the importance of consistency and of working together to achieve a common aim; to support the service user. Thomas also illustrates this in the following extract:

Extract 4c.14 – "I think that usually the houses can deal with their clients if they are talking, if they are working in a team they can deal with their clients and they can help them." (Thomas, paid carer)

These comments explicitly state the importance for teamwork and communication within the immediate care environment. Thomas's conception of teamwork here seems to reveal a sense of self-reliance and confidence in the skills of residential care staff. Miranda also reflects this attitude:

Extract 4c.15 – "To be perfectly honest...for *me* and the proprietor of the home, we are both experienced and qualified nurses so really and truly we *knew* how to deal with X's behaviour." (Miranda, residential care manager)

In this case, Miranda refers to previous experience and training. The skills she has developed in the past are useful for her and for the people she works with. Care workers and professionals also look to their peers for advice:

Extract 4c.16 – "we draw our own help and experience *within* the team from managers, right the way down." (Sarah, day services worker)

Sarah also discusses the work of the Behaviour Therapy Team and how it has helped a particular client who she works with at the day centre:

Extract 4c.17 – "It has been good because we've been sharing...ideas, information and...sort of come up with different things for us to do like

moving times for X to come in, if that works better.” (Sarah, day services worker)

In this instance, she explains how she tried to arrange for a particular service user to arrive at the day centre at a different time in the morning. Here she can be seen to conduct a small-scale experiment with the service user; a trial and error process. This form of problem solving was mentioned by other carers too, Sally recalls her problems with the sleeping patterns of one of the residents in the nursing home that she manages:

Extract 4c.18 – “when you’re looking at *anybody’s* problems you kind its...to make a stab in the dark [laughs], when you when the doctor tries to diagnose you’re looking at all kinds of evidence to come up with a conclusion and come up with a treatment for the person and it doesn’t matter what’s happening, whether it’s a behavioural or a psychiatric or organic problem it’s the same thing, you’re just looking at all kinds of...ways.” (Sally, residential care manager)

Sally was a trained nurse and this may be the reason why she related her situation to that of a doctor who looks at the facts and then attempts to solve the problem. I find the phrase ‘stab in the dark’ to be particularly interesting here. I believe that she is implying that often the solutions to some of the complex problems that affect people with intellectual disability are not easy to find. The input, support and ideas from others are needed to find solutions, almost through a process of trial and error. The following extract from Tracey illustrates this approach to problem solving well; she is describing the role of the psychiatric nurse:

Extract 4c.19 – “They tend to come out and do an on-the-spot assessment and ask a lot of questions, meet the person, speak to the person, get a feel for what the problems actually are and then ... they’ll draw up a report and that will go to whichever agency they feel is most appropriate, that might be the psychiatrist, it could be the behaviour team, it could be speech and language and in some instances it has actually been all three, and so it’s like they seem to be like the first point of...the

first port, port of call really with a link between us and the other services and that's how I've viewed them." (Tracey, residential care manager)

In this particular situation, the psychiatric nurse appears to provide a link to trying various solutions for a problem. This extract also shows that a residential care manager such as Tracey is likely to be experienced with the process of accessing professional help. She seems to have detailed knowledge of the role of certain professionals within the referral process. She appears to know the process for accessing help and services. I believe that it would be difficult to imagine a family carer being able to describe this referral process with as much detail.

However, as always, paid carers were keen to remind that all problem solving activity took place within a context of limited financial resources. Philippa is referring to the difficulties in finding residential placements for people detained under the Mental Health Act (Department of Health, 1983):

Extract 4c.20 – "we find placements, but then you've got all the paperwork that involves the place...placements things, you've got the referral, then you've gotta wait for the funding, and then you see the place and then the funding is turned down and it all starts again and it takes forever." (Philippa, paid carer)

This quote indicates that the funding does not seem to be available at times when it is most needed. It is uncertain whether funding will be available. I have interpreted Philippa's comments as a suggestion that this inconsistent pattern of funding is an inefficient way of working. Again, the difficulty of financial resources for this population may make it difficult to work efficiently. However, there appeared to be a certain amount of creative team working amongst paid carers. One of the ways in which a problem could be solved was to try various approaches, in this context; one of those approaches may be the participation in an RCT.

### 4c.3 Perceptions of research

Like the other stakeholders, paid carers appeared to have positive views about research. In particular, it appeared to be viewed as a process that could inform future planning:

Extract 4c.21 – “looking into facts and figures about whatever the topic might be and...gathering as much information as possible to plan for the future.” (Tracey, residential care manager)

Extract 4c.22 – “if you don’t do research how are you gonna learn? And make it better for the next lot that come along” (Sue, residential care manager)

Extract 4c.23 – “Without research you’re not finding out new information and you can’t make your way forward can you?” (Philippa, paid carer)

The emphasis on the future is interesting. Paid carers may come into contact with a great variety of service users who spend various amounts of time within the residential unit. Therefore, longer serving staff members may be able to see the process more clearly than family carers or service users. The ‘next lot’ as referred to by Sue may be a familiar sight for these carers. Therefore, it is possible that paid carers may find it easier to take a broader picture of research than family carers. However, they were similarly concerned about the purpose of research:

Extract 4c.24 – “Some of these people that do these researches and I’m not putting them down, I just feel that they *need* to come and actually stay and *work* with these people and get to know them and get to find out...you know...their day-to-day lives and their day-to-day actions and the sort of things that can upset them and can make them happy. [...] researches need to be done, *all* the time, and...I really am into researches. But it’s the outcome, it’s what...comes *out* of the research that I tend to sort of look at and think, ‘nah they’ve not done this properly’

or 'someone who's done this has never ever *dealt* with what they're trying to research'." (Emily, paid carer)

Emily's appears to criticise a research approach that maintains a distance from its subject. She seems to prefer a more integrated research process that reflects the everyday aspects of the participants' reality. The distinct, abstract nature of research appears to frustrate her:

Extract 4c.25 – "I think you've got to be more hands-on" (Emily, paid carer)

Like other stakeholders, the link between research and practice was seen as important. Miranda implies the link between research and practical outcome directly in the following extract:

Extract 4c.26 – "'Research' [...] people talking to other people professionals, getting as much information as they can, collect...data from all means and actually come out with a practical solution to whatever they're looking for." (Miranda, residential care manager)

For Miranda, the process of gathering information and the process of acting upon that information are interlinked. Thomas emphasises his attitude to research in relation to his experiences with practical outcomes:

Extract 4c.27 – "I have a positive attitude towards research on people with learning disabilities because I read a book where...there were very many positive examples of how the research changed the work practice for the be...better for the best of this client group. Those examples have showed me that to *improve* their life it was necessary to do this research. I think that's why I'm so positive about it." (Thomas, paid carer)

Thomas describes his positive feelings about research in relation to a book he has read, which highlighted practical implications. He equates the positive influence on work practices to improvements in clients' quality of life. This quote also underlines the importance of research dissemination. His has read

about the research from the material available. Not only this, but the practical solutions and implications were communicated to him. This does not appear to have been the case with Emily:

Extract 4c.28 – “who deals with it? where does all these figures go to? where does all these answers go to? who’s gonna accumulate all these answers? [...] And I don’t know whether you will be finishing it off or whether someone else will, but it’s always that *last* little bit that *really* gets me, and I think to myself, no you’ve *not* really looked at this properly, this is *not* what should’ve come out, but then I’ve got my own opinions and ideas.” (Emily, paid carer)

Although overall, Emily seems to have positive attitudes about the concept of research, she seems to feel disillusioned by the end product. Emily’s comments indicate that she feels isolated from research outcomes. These extracts highlight the importance of disseminating research outcomes to paid carers in order to improve their understanding and acceptance of the research process.

Broadly, practical research within services for people with intellectual disability was perceived in two ways; maintenance and development, with emphasis on the former. Maintenance refers to the process of monitoring and quality assessment, ensuring that individual services perform adequately. Development refers to the further-reaching process of evaluating and improving services. The following extract shows both of these ideas, often seen as a requirement and a pre-requisite for improvement of services:

Extract 4c.29 – “I think there is always space for improvement so somebody thinking about checking the services, that it is working right, this is valuable and also even if it comes out that the service is OK maybe doing this research there are topics raised which...how the service could be improved.” (Thomas, paid carer)

Thomas describes the process of service maintenance. The services need to be monitored adequately through external checks. Also, he appears to see

research as a method to highlight potential problems and areas for improvement, thus helping to develop the service. The following extract shows similar thoughts:

Extract 4c.30 – “I think to help improvement, continuous improvement you know, yeah we all have to look at what we’re doing to see whether we’re meeting the criteria we should be so...and to make things better for the people that we’re supporting.” (Lucy, residential care manager)

Like Thomas, Lucy seems to see improvement as a potentially limitless process. Lucy appears to imply a certain moral obligation to monitor and assess services, to provide the best possible service for residents. Tracey offers a similar opinion about assessment and service monitoring:

Extract 4c.31 – “Well I guess *everything* is assessed for its effectiveness, whether we like it or not, and, yeah I see...I *suppose* it is necessary because you could be throwing money away in the wrong direction, by somebody outside looking at the situation they may be able to come up with ideas and ways of things being done differently that would benefit everybody.” (Tracey, residential care manager)

Tracey links the process of service maintenance to the provision of resources. She demonstrates a belief that research and external assessment may be necessary to improve the service. Other interviewees saw the process of accountability and service monitoring as a sign of the times:

Extract 4c.32 – “Yes, I mean all services are assessed and we live in an age where we have to get used to that. It helps with quality control and making sure that you’re actually doing what you’re meant to be doing, I think. [...] Not very nice, but...[laughs].” (Sally, residential care manager)

Sally indicates that she thinks that this type of service monitoring is a necessary evil. She mentions the need to maintain service quality and service integrity. This implies a belief that services may deviate from initial aims, providing a



further reason to monitor them. This idea is phrased slightly differently in the following extract:

Extract 4c.33 – “I think they need to be kept on their toes; I think yeah otherwise they tend to sit back and...don't *really* push it, if you know what I mean? [...] I *do* think that they need to look at what they're doing, how they do it, more frequently. I think they don't, they tend to sort of stay in a rut.” (Emily, paid carer)

Emily had a less positive attitude towards intellectual disability services than many of the other paid carer interviewees. Her comments here can be seen to relate back to the perceived lack of financial resources. In this context, interviewees' common perceptions about the need for service monitoring become clear. Intellectual disability services need to be accountable for their actions in order to provide the best possible service where resources are limited.

#### **4c.4 Communication and informed consent**

One of the major hurdles faced by paid carers is trying to facilitate communication between themselves and the person with an intellectual disability. This is particularly a concern where the service user may have more severe intellectual disability. Carers who have daily contact with service users may be best placed to facilitate this communication:

Extract 4c.34 – “some service users its difficult for people who don't work with them regularly to know whether they are understanding, but I think if people *are* working with them regularly then you can always find a method to communicate with them, but it depends on what level.” (Lucy, residential care manager)

Lucy claims that people who have not spent much time with each service user will find it hard to communicate. Her position as a carer allows her to develop relationships with service users based upon regular contact. She also refers to

levels of communication, and discusses the individuality of communication challenges:

Extract 4c.35 – “Erm, yeah just methods of communication, Makaton, Widget, pictures...there’s all different kinds of software that you can use. [...] but only when the service user understands it, you can do a lot of work with Widget and not every service user would understand that, they’d need say pictures or something else.” (Lucy, residential care manager)

Lucy mentions several communication methods which could be useful for interacting with service users. The potential problem being that different service users appear to understand different communication methods.

These problems with communication have implications for the research process. Firstly, the service user’s subjective opinion is considered to be the ideal standard for improving research accuracy, but this is not always possible given the circumstances:

Extract 4c.36 – “I think it’s very difficult because...if you need information about people with learning disabilities it would be great if they could all give their input because you’d get it right from the horse’s mouth so to speak, but because so many of them have communication problems its reliant on the information that people like myself and the *staff* give to you and you have to rely on us being honest and accurate so...I mean I guess it’s quite difficult to *judge*.” (Tracey, residential care manager)

Tracey expands upon the notion of obtaining accurate information for the research. She mentions the problem of giving answers on behalf of service users who have difficulties with communicating. She discusses the difficulties she experiences when attempting to provide accurate answers, which are limited by the carer’s own ability to judge how the service user feels. Sue corroborates:

Extract 4c.37 – “Everything is done on *my* perception of them, which not might be the *right* perception.” (Sue, residential care manager)

She expresses concerns about the subjectivity of her own perception of how a service user feels. Philippa summarises this problem succinctly:

Extract 4c.38 – “there’s an awful lot of carers that have different opinions” (Philippa, paid carer)

The importance of communication is paramount. Paid carers expressed a desire to accurately represent the views of service users. This relies heavily on how carers and service users are able to communicate with each other, and can affect perceptions of how accurate research can be. Nevertheless, difficulties in communication between service users and other stakeholders have other important implications, since they preclude difficulties in obtaining informed consent to participate in research. For Sue in the following extract, the closeness of the relationship will better aid and offset the problems surrounding communication.

Extract 4c.39 – “*Only* people that really know them and work with them on a daily basis [...] because we know what we’re signing for and we know *why*” (Sue, residential care manager)

In this extract, Sue describes the need to involve people who have daily interaction with the service user. It is interesting to note that she says that these are the only people who will be able to provide meaningful permission. In a sense, this approach to seeking consent has paternalistic tendencies. However, paid carers were often somewhat cautious:

Extract 4c.40 – “we act in their best interest, or what we *think* is their best interests, and we try and make that judgment on their behalf.” (Tracey, residential care manager)

Tracey highlights one of the problems of gaining consent, again the problem of subjectivity. She relates to the standard of ‘best interest’ here. She admits that

there might be a distinction between a carer's perceived best interests and the wishes of the service user. As she says, there is no clear-cut method of determining this.

Approaches involving third parties were commonly used if the service user was perceived to lack the ability to provide informed consent. An exhaustive approach to proxy decision making involved gaining a consensus from stakeholders who were involved in the service user's care, many saw this approach as preferable:

Extract 4c.41 – “it isn't *just* relating for people with a learning disability it's for the general population as well, and people will consent many times without having the real understanding, and when you take that to a person who has that degree of problem with their, you know their thinking process it becomes that much worse, and that's when you *really* need to look at involving more than one person, and nobody can consent for another person.” (Sally, residential care manager)

Sally relates the problems of consent to the general population. In her opinion, problems with understanding and consent are not unique to people with intellectual disability. However, she does suggest that problems are confounded by the presence of an intellectual disability. This relates to her preference for a consensus-seeking approach to the consent procedure. The following extract relates this to official legislation:

Extract 4c.42 – “The new Mental Capacity Act that's come out [laughs], which I don't know too much about yet even though we've only got 'til April. Ummm, but you've gotta involve *them*, professionals and families.” (Helen, residential care manager)

Interestingly, the above extract is one of the only times that the Mental Capacity Act was mentioned in the interviews. This Act has since made independent advocates mandatory for people with no legal guardian. Helen refers to changes in policy affecting the consent process for people who lack capacity to provide informed consent. Helen's comments indicate that she has not always

employed a multi-disciplinary consensus in the past. Tracey describes the process by which she thinks consent should be given:

Extract 4c.43 – “if people are *able* to give their consent then they obviously should be asked for it, if we had concerns about...acting on behalf of somebody then I would probably speak to the parents if they have parents for their views, if they haven't got parents I may well speak to the care-manager to see whether the care-manager agreed that it was appropriate, I think *generally* we've got other people involved who already *do* believe that it's appropriate.” (Tracey, residential care manager)

Tracey appears to describe a stage-based procedure for consent decisions. She acknowledges that service users may not have contact with immediate family members. She stresses the need to involve a variety of people and come to an agreement. Beatrice has a similar view:

Extract 4c.44 – “I think the whole team, *if* the person with the learning disability doesn't understand or won't agree, the whole team have to get together and find out, you know how we're gonna work around it.” (Beatrice, day services manager)

This extract re-emphasises the importance of teamwork amongst those who work closely with people with intellectual disability. The consensus-seeking approach to decision making involves teamwork. It is interesting to see her choice of words, 'working around' the consent issue. This implies that practical decisions about permission and consent are taken with a degree of flexibility in order to achieve an outcome for a service user. Miranda offers her opinion:

Extract 4c.45 – “I think a good consent procedure would be the key people *working* with the client himself or their selves, the people that are important to the client in their lives, and I think they are the best people to be able to *make* that decision but I don't mean doctors, consultants and people like that who only sort of see them for maybe 10 minutes, 15 minutes in a month.” (Miranda, residential care manager)

Miranda does appear to be describing the process of consensus seeking, but she distinguishes the people whom she would like to provide that consensus. She draws distinctions between the health professionals and paid carers. This extract essentially describes a consensus-seeking approach based upon closeness of the relationship. In her opinion, the most meaningful relationships are likely to exist between carer and the service user. Therefore, she places the onus of consent decisions first on the carer.

Within a more restrictive environment such as an inpatient ward, consensus approaches to consent may be more difficult to achieve. The following extract describes Philippa's experiences of making proxy decisions about treatment for service users within this environment:

Extract 4c.46 – “I think it's a case of a little bit of common sense as well, it might be, you know...in all the policies now about consent, but there is times when you've *got* to use a bit of common sense and you know this person *doesn't* understand the dangers that are involved if they don't consent to whatever it is that you know, you're asking them to do.”  
(Philippa, paid carer)

It is clear that this extract does not refer to a decision about research participation. This participant's job at the inpatient ward may mean that she witnesses emergency treatment situations regularly. Emergency situations require emergency decisions, and taking action by proxy is useful for making these decisions.

#### **4c.5 Perceptions of the trial**

The paid carers who were interviewed had all cared for a service user who had been participating in the RCT, seven had seen the service user(s) randomised to the intervention arm and four had seen the service user randomised to the control arm. With regard to the rationale behind the study, many interviewees appeared to have similar beliefs to that of the researchers; to evaluate a service for people with intellectual disability who were displaying challenging behaviour:

Extract 4c.47 – “my thought was that to be to look at the Behavioural Therapy Team and their effectiveness.” (Tracey, residential care manager)

Extract 4c.48 – “checking the services, that it’s working right” (Thomas, paid carer)

However, some carers conceived the rationale differently; the following extract shows confusion about the role of the researcher. Miranda appears to have created an alternative explanation of the trial process:

Extract 4c.49 – “my understanding was that you came here, took back as much details about the incident of the concerns we had with X, then you would then feed it back to the main core, the main centre then it was from that that they would decide whether the input or who would be selected.” (Miranda, residential care manager)

Miranda appears to hold erroneous beliefs about the process of the RCT. She believes that the information she has given during research assessments has influenced the allocation of the service for the service user. This extract also shows that without understanding the rationale behind the study, it would be difficult for carers to fully understand the RCT procedure.

One of the most fundamental and easily understood aspects of the RCT procedure was the need for a comparison group. Sarah and Sue consider the use of comparison groups after being shown a vignette that served as a reminder of the RCT method:

Extract 4c.50 – “I suppose it would have to be done like that so you’d get something to compare...” (Sarah, day services worker)

Extract 4c.51 – “How else would you do it?...Because you’ve got to get...a different perspective haven’t you? For the group that has been helped and the group that hasn’t, it’s a bit like taking a placebo innit?” (Sue, residential care manager)

Interestingly, both Sue and Sarah cared for service users who were randomised to receive intervention. One element that can be seen in both extracts is a belief in the necessity of comparison groups in order to perform an evaluation. After being shown the vignette of the RCT, Thomas offers his opinion:

Extract 4c.52 – “it’s just the way to conduct research, it’s impossible to...err, if you want to test effectiveness like of the therapy team and the other, any other approaches, err like I know that this, I know is the only way to check that they are working.” (Thomas, paid carer)

Thomas also sees the RCT as the only viable method to demonstrate the effectiveness of the intervention. Thomas had prior knowledge of science and research from university which may affect his attitude. However, for those who had not fully understood the reasons behind randomisation, the procedure sometimes seemed difficult to accept:

Extract 4c.53 – “I really don’t know, I’ve no idea, someone decided somewhere that...computers can pick, it’s like picking your numbers out of the lottery...and, it’s just not right. [...] Only that some boffin decided that it’s a good way of doing it. I don’t know, I really cannot see the reasoning for that.” (Emily, paid carer)

This extract indicates the interviewee’s distrust of randomisation, from the perspective of a participant who has not understood the reasons behind the process. Even in cases where the procedure was understood, it was not necessarily popular, though there may have been a belief that it was a necessary evil:

Extract 4c.54 – “I *don’t* think it should happen but I can see that there may be a need to do it to...to try and get some sort of evidence it’s a bit like giving somebody a placebo pill and somebody the treatment, you don’t see how effective something is unless you do those sort of trials, so as I would rather it *didn’t* have to happen like that I can see the need for it.” (Tracey, residential care manager)



Unlike Emily, Tracey appears to accept the method through her perception of the necessity to allocate some participants to a comparison group. However, she displays reservations. On balance, she appears to suggest that the need to find evidence for treatments and interventions is a sufficient reason to employ random allocation. However, the downside is that this may be perceived to compromise fairness for individual participants:

Extract 4c.55 – “I would have thought that they were probably thinking they were being fair and...sort of giving everybody a chance to receive that service, but I don't think they've actually thought it out well, as to whom they feel needed the service.” (Miranda, residential care manager)

Miranda offers her views on the fairness of the RCT procedure. She suggests that the rationale behind the procedure was to ensure fairness to individual participants who tried to access the service. However, in this context, she sees randomisation as a flawed alternative to prioritisation based upon individual need. Fairness, therefore, can be highly subjective:

Extract 4c.56 – “I think that there's gonna be people because they didn't get put into the group that they want to who would think it would be unfair because they didn't get the service that they wanted.” (Lucy, residential care manager)

The above extract highlights an important point that is implicit in many of the extracts above. Perceptions of the fairness of the trial reflect participants' preferences to be allocated to one group over the other. The concept of fairness is therefore seemingly related almost entirely to participants' ability to access their preferred services. However, in another extract Lucy appears to describe something akin to equipoise:

Extract 4c.57 – “the *other* service might work better for them than *that* service did, so its swings and roundabouts really, innit [laughs]. Erm one of the people who was with the Behaviour Therapy Team could've benefited better from the other one, so, you never know.” (Lucy, residential care manager)

Lucy's position rests upon the suitability of the intervention for each individual. This relates to the individuality of people with intellectual disability, and the fact that different approaches may work for different service users.

Lastly, it is again necessary to show how the RCT was linked to stakeholders' perceptions of resources, Helen, describes her views on the process:

Extract 4c.58 – “they do this research to cut back [...] Say this research said that the 30 picked randomly, was it yeah, 30 that were picked random...improved or they didn't have to go into secure units or whatever, then if you was fighting for the cause you would say it is worth it, *but* if you was fighting to make cut-backs you would say something like the 30 that weren't on it never had to go into secure units either so. [...] Or what they, what they initially wanted the research for, and if it's to prove...one theory or another.” (Helen, residential care manager)

Helen appears cynical about the rationale behind the RCT, and she uses this to cast her doubts upon the process itself. She states that the researcher will interpret the findings according to their own agenda. To her, those commissioning the RCT were motivated to reduce funding for services. As described throughout the analysis, beliefs about resources and funding were very important to all stakeholders.

#### **4c.6 Motivation to participate**

When discussing why paid carers decided to encourage participation in the RCT, it is important to pay attention to both their levels of understanding, and any difficulties they may have had in obtaining help. Were participants acting in accordance with altruism or with their own interests? The following two extracts express the importance of self-interest in making decisions to participate. This was a common viewpoint amongst carers who were seeking help:

Extract 4c.59 – “I suppose I was hoping that if we might get a bit of extra input [laughs] from the Behaviour Therapy Team, but I knew that that

wasn't the remit of it but I just thought it might do." (Sally, residential care manager)

Extract 4c.60 – “the *waiting list* for the Behaviour Therapy Team was so long, that in our particular case we were...if that had been the scenario, it would have been worse, yeah you take a chance on it.” (Beatrice, day services manager)

These extracts confirm a preference to be allocated to the intervention group over the control group. In both cases, the carers appear aware that the service user may not be given the help and support. Conversely they appear to be willing to participate in order to gain extra input. Beatrice suggests that access to the intervention could be facilitated by participating. In her case, she perceived that randomisation to the intervention group would eliminate a waiting list. This she sees as a potential gamble, but one that is worth taking. Helen offers a similar viewpoint:

Extract 4c.61 – “we was having trouble getting a behavioural therapist and we agreed to the program [laughs] because we thought we've...at least get a better chance of getting a behavioural therapist. [...] We agreed to this on purely selfish reasons [laughs].” (Helen, residential care manager)

Helen's motivation for participating matches that of Beatrice. She alludes to problems of gaining access to services, which is a major concern in the climate of limited financial resources. Participation in the RCT provided a unique opportunity for service users and carers to gain access to a service:

Extract 4c.62 – “I thought it would be a means to an end for my service user. If I thought that it was gonna get the behaviour team through the door quicker then I would've signed up to anything, research...anything that I was asked to really.” (Sue, residential care manager)

Like Helen, Sue's emphasises the needs of individual service users. This extract suggests a tone of desperation and opportunism; she says that she will

sign up to anything in order to access help. However, some paid carers did describe altruistic motives for taking part:

Extract 4c.63 – “I think it’s good if it’s gonna help to improve the services so I was happy to...to help.” (Lucy, residential care manager)

Extract 4c.64 – “I had no problem, anything that makes services better has gotta be good.” (Tracey, residential care manager)

These two extracts shown above suggest altruistic motives. Also explicit within these extracts is the desire to help improve services for people with intellectual disability. Thomas expresses similar views:

Extract 4c.65 – “I said the trial shows some things which have to change in the service, those people who had received the service will benefit, and those people who took part will I suppose benefit indirect because sooner or later they might come back to the more improved Behaviour Therapy Team or another service.” (Thomas, paid carer)

Thomas hints at the importance of indirect service user benefit. He refers to the cyclic nature of service user problems, and suggests that some service users may require similar services again in the future. If this is true, some of the service user participants may actually benefit from the RCT directly. This perception appears to be consistent with the idea that research influences provisions in the future.

#### **4c.7 Summary**

Paid carers appeared to have a wealth of experience working with service users, and were well linked into local professional services. However, they also described the challenges of limited resources in the area of intellectual disability. For this reason, paid carers seemed to be opportunistic and realistic about the way in which they sought to solve problems that arose, looking first within their

own teams before reaching out for external professionals. This attitude towards problem solving often attracted them to participate in the RCT, because of the chance of receiving extra help through the intervention group and bypassing a waiting list. However, they were often confronted with difficulties regarding service users who did not have capacity to provide consent, and many preferred to seek consent through consensus with other significant stakeholders. They acknowledged good relationships with service users, but were sometimes concerned about their own ability to talk on a service user's behalf.

Like all the stakeholder groups, paid carers were positive about research in intellectual disability. They tended to have slightly better understanding of RCT concepts than family carers, although this was not universally true, and misunderstanding the key trial concepts appeared to cause anger and frustration with the trial. The following sub-chapter will discuss the opinions of health and social care professionals.

## 4d. PROFESSIONALS

The professionals represented by far the largest and most diverse group of stakeholders in this study; including nurses and social workers of various grades, psychologists, psychiatrists, occupational therapists, speech and language therapists, and community support workers. Accordingly, collectively their views tended to be more complex and varied than the other groups. The professionals who were interviewed may have been employed by either the NHS or by social services; however they often worked across these boundaries in multidisciplinary teams. Some of those interviewed had direct experience of working with the REBILD trial, and others had indirect experience as they had been part of a team that had been involved with the trial. Sub-chapter 4d attempts to collect their experiences cohesively.

### 4d.1 Perceptions of disability

Much like the paid carers described in the previous sub-chapter, professionals' views of people with intellectual disability tended to draw influence from the individuality of each service user, and from the social barriers that they face. From an individual perspective, the service users in this study were often seen as complex individuals:

Extract 4d.1 – “X is a very complex character [...] to get something very subjective from him it's very difficult because of his learning disability.”  
(Andy, nurse)

Extract 4d.2 – “these people are sort of highly, highly complex individuals” (David, social care professional)

There is a broad range and variety of ability which overlaps with personality differences, creating complex individuals who may be difficult to make generalisations about:

Extract 4d.3 – “People’s brains are so variable and the amount of damage to people’s brains is so variable” (Janice, professional service manager)

Extract 4d.4 – “With the knowledge that comes with learning disability training, understanding that not all medications suit every person with a learning disability. If...there are very subtle breakdowns in the pathways in the brain, the electrical impulses that aren’t getting through then the medication that we’re putting into somebody may not get to the point we want it to get to in the first place.” (Mark, nurse)

I interpret Mark’s extract as indicative of professionals’ views that this is a complicated group of the population. These extracts suggest that this is possibly because the brain pathways occurring in the average brain may be disrupted in people with intellectual disability. This knowledge was linked to how professionals saw people with intellectual disability in a social context. Like service users and carers, professionals related to issues of labelling and societal disadvantage. The meaning of such a label was questioned, since people with intellectual disability were seen to represent a complex and diverse population:

Extract 4d.5 – “it is *such* a varied group of people *anyway* that we’re just labelling with one label. Erm it can be...virtually *meaningless*” (Alice, professional therapist)

Like the paid carers, professionals who work with a wide variety of service users are able to see the limitations of labelling people with intellectual disability as one population, and were often more conducive to seeing the population from a social perspective:

Extract 4d.6 – “I’m a firm believer in the Social Model of Disability and the main impact for learning disability *isn’t*...the *individuals*, it is everybody else impinging on the individuals, and so my *problem* would be that I think that learning disabled people begin to be disadvantaged the minute their parents discover they’re...and *continue* to be disadvantaged all the

way through their childhood, their education.” (Janice, professional service manager)

Extract 4d.7 – “people can be labelled as having behavioural difficulties when they haven’t *really* got behavioural difficulties. Emm, quite often the root causes are communication difficulty, not being able to *express* themselves properly...institutionalised behaviours which...people...so maybe they’ve never had attention, and...they’re put into this box which isn’t a good place to be in [...] nobody wants to work with you...you’re seen as something *special* rather than just an ordinary individual...you’ve got all these *guidelines* written about you, you’ve got frequent meetings being held about you...it’s just a very impersonal service if you get that label.” (Natalie, social care professional)

Rejection and disadvantage were common themes throughout the interviews. Janice refers to the problems that people with intellectual disability may have after they begin to display limitations within society. She frames this belief within the Social Model of Disability (Oliver, 1983). The social model proposes that the concept of disability is constructed through an individual’s interaction with society; the conscious and unintentional reactions of society will serve to exclude and marginalise the individual from research activity. This model exists in opposition to the medical model of disability, which suggests that disability is related to conditions or illnesses that are intrinsic to the individual. The contrast between these models has implications for clinical research, which largely relies on the medical model.

Natalie refers to the labelling that occurs within professional intellectual disability teams, and in doing so she seems to show some disenfranchisement with the service. Implicitly, Natalie also relates to the Social Model of Disability. Social disadvantage arises through difficulties in communication, which leads to particularly challenging service users being labelled with behavioural difficulties. Natalie and Janice refer to an inevitable labelling which will lead to problems within society. Elaine relates this disadvantage to the world of research:

Extract 4d.8 – “I think that too often they can get *excluded* from



research by research ethics committees in the same way that children would often be excluded.” (Elaine, professional therapist)

Elaine provides information about how people with intellectual disability are disadvantaged. Elaine’s comparison with children can be interpreted to illustrate protectiveness in society, which could have negative consequences such as exclusion from research activity. The concept of over-protection is indicated more clearly in the following quote:

Extract 4d.9 – “I think that we view people with learning disabilities in a very disadvantaged way because they can’t voice for themselves they actually depend on other people to voice or advocates for them, and they themselves wouldn’t raise the issues [...] I think we feel that we are quite protective over this you know this group of people.” (Julie, nurse)

Julie refers directly to social disadvantage and links it back to the concept of protective attitudes amongst professionals, which may affect access to service users as research participants. This could be seen as creating a vicious circle in which service users are labelled by society and then become socially disadvantaged and isolated. Importantly, she also states that people with intellectual disability do lack certain abilities. Highlighting a point such as this may seem like stating the obvious, but it should nonetheless be discussed along with any assumptions about labelling and disadvantage caused by society. Many interviewees claimed that people with intellectual disability lacked the ability to undertake certain tasks, as Andy exemplifies:

Extract 4d.10 – “It’s just because they just cannot express their emotions, their feelings, their wishes and all that yeah, not all of them but some of them yeah.” (Andy, nurse)

Regardless of the debate about service user ability, the link between labelling and disadvantage appears clear for people with intellectual disability. From this position of social disadvantage, professionals may adopt a well-meaning protective attitude which inadvertently labels these people, and excludes them further from activities such as research.

## 4d.2 Perceptions of research

Research has different meanings for different people, but there exists common perceptions about the process, aims and outcomes of research. Before discussing professionals' perceptions of research in detail, it is important to note that interviewees in this study shared significant disparity in their amount of prior knowledge and experience with research. Some professionals had no prior experience at all; others had knowledge of research methods through university or through previous training. Some professional interviewees had practical experience of conducting research, and of these, some had conducted research involving people with intellectual disability. Therefore, professionals tended to have wider perspectives regarding research than other stakeholder groups:

Extract 4d.11 – “I suppose that’s a process that you go through to try and [...] fulfil a hypothesis in the scientific sense I suppose, but it’s an *investigation*, should be an investigation.” (David, social care professional)

This extract highlights a common research definition amongst professionals: the process of investigating, or gathering information about a topic of interest:

Extract 4d.12 – “I feel that research is a *process* that can take many different forms and that is carried out by people who know lots about research and *enjoy* it” (Andrea, nurse)

Research for Andrea is the process of answering a question. I take her comment to imply that she sees research as a process that is done behind the scenes, by those who have specialist knowledge. This perception creates a distinction between research and the clinical work which is done by nurses such as Andrea. Catherine describes this distinction more clearly:

Extract 4d.13 – “I’d rather do the hands-on work than sit and do all the studying so I suppose it might well be that there are a lot more people like me and or it could do with hiring and funding and those sorts of

things but, I have to say I'm not *hugely* academic so I don't want to sit and *do* the research, do the studies." (Catherine, professional therapist)

Catherine's comments define a distinct role for research to play. She contrasts 'hands-on' work of community teams with 'academic' work of researchers. All professional interviewees expressed positive views about research at some point during their interview; it was thought to be needed in this field:

Extract 4d.14 – "there's quite a *lack* of research within learning disabilities and that's a problem." (Catherine, professional therapist)

Extract 4d.15 – "there's a lot of *knowledge* but there's not the research to back up good practice I think." (Charlotte, nurse)

Charlotte distinguishes between knowledge and research. I interpret knowledge to be an internal resource possessed and shared between staff, as part of a team. Research appears to be less direct, but required to support staff work. Oliver also emphasises that professionals in the services need help to conduct research:

Extract 4d.16 – "We need to have more of it; I *really* believe that the universities ...should've been helping us out a hell of a lot more over the last couple of years." (Oliver, professional service manager)

Oliver feels that links should be made between services and universities to support research. Intellectual disability services may experience isolation from traditional research institutions. Mark summarises his belief about the position of research in this field:

Extract 4d.17 – "It's a very important area for the obvious reasons that learning disabilities services have progressed so much in the last twenty to thirty years that...and again there has been very little research apart from in very key areas." (Mark, nurse)

Here, Mark emphasises the importance of conducting research in this area. He appears to believe that research has failed to develop at the same rate as the services.

Nevertheless, research was perceived as a process done by specialists, distanced from their subject. The majority of negative views related to research without an aim, goal or end product. In a similar way to the carers' perceptions, the concept of research purpose was important:

Extract 4d.18 – “It’s useful providing its specific and geared towards...problem areas I guess, if it’s not specific it’s a bit pointless.”  
(Hannah, social care professional)

Extract 4d.19 – “I think it should be something that’s got a purpose. You almost need to have a plan before you research as to what you’re looking for and how you’re gonna use it. It shouldn’t be *aimless*, that’s the word I’m looking for. I wouldn’t like it to be aimless.” (Christine, nurse)

Extract 4d.20 – “Yeah I mean as long as it isn’t...research for the sake of research, if there’s a *goal* and its gonna move the service on, fine, you know.” (James, social care professional)

These extracts imply that viable research needs have a specific goal and follow up with practical solutions that will be of use. Conducting research without any discernable aim or benefit will not appear to earn respect amongst this community. These comments indirectly indicate that many professionals seem to take an active interest in research, which may be true:

Extract 4d.21 – “it would be interesting to see the results of the research and, I suppose it will be published at sometime?” (Nicholas, social care professional)

Extract 4d.22 – “so we could see the whole report by next year?” (Julie, nurse)

These extracts demonstrate an interest in the outcome of the RCT they have worked alongside and been involved with. This emphasises the need to communicate the outcomes of research appropriately, Andrea embellishes:

Extract 4d.23 – “I like to read the finished product, I’m not really a person that enjoys research to be quite truthful but...I can’t. I like reading the findings and the recommendations that people *make* to improve practice [...] its more about the recommendations and changing practice, for *me*...but not necessarily the actual process that you have to go through to get them recommendations.” (Andrea, nurse)

In this extract, Andrea indicates her lack of interest in the research process itself. However, she does show an interest in the research outcomes. She implies the importance of disseminating, or communicating research outcomes among the professional nursing teams. Christine elaborates:

Extract 4d.24 – “otherwise you’re gonna end up doing the same research over and over again throughout the country. I’m not..you can’t generalise everything, but I think some things you could, and it’s like kind of re-inventing the wheel. [...] if they *weren’t* well publicised it would save up people doing that work again.” (Christine, nurse)

Christine seems to relate dissemination to financial resources. She highlights the importance of dissemination to increase efficiency. Oliver offers his opinions from the perspective of a service manager:

Extract 4d.25 – “if the outcomes are really good, then this piece of work, really needs to go to every learning disability service in the country, they will make their own minds up that is, but it’s up to us to ensure that we publicise it good enough, because we *need* to get it on people’s desks, it’s not just letting them find it, it’s us putting it on the desk.” (Oliver, professional service manager)

Oliver appears to see dissemination of research outcomes as an active process. He wants to see that the outcomes are broadcast widely throughout similar

services. This was a common belief amongst health and social care professionals:

Extract 4d.26 – “the main one [aim] is to do the research to see in what way we can improve the *service* and if possible get that published so that would disseminate the findings to other professionals.” (John, nurse)

Extract 4d.27 – “to me research is about finding out isn't it? Finding out what works and what's not worked and it's not just about...just for you it's about sharing that information with, I dunno nationwide, worldwide? Yeah so we can learn from *people*.” (May, nurse)

Dissemination seems to be the process of sharing information. Conceptions about the scope of research varied throughout the interviewees. Some interviewees related it to themselves, some related to the immediate local area, or the country. May was one of the only interviewees who explicitly mentioned global implications of research. For professionals above all other stakeholders, there seems to be an intense interest in research outcome, how the research findings will be used, and how they will benefit people. The idea of research benefits came across strongly when discussing the possible beneficiaries of the RCT:

Extract 4d.28 – “the behaviour therapist service themselves. They could actually say that ‘look this research actually indicate that our treatment, our therapy service is useful’, therefore they could actually...present that to the Trust board maybe you know asking for more people for extending their staff group and extending their service.” (Julie, nurse)

This extract shows research in relation to how it may affect funding provision in the future. Julie says that positive results from the RCT could lead to increased resources being made available from high level organisations, such as the NHS Trust. John espouses a similar process:

Extract 4d.29 – “I think everybody will benefit, service users of course they will benefit right, will benefit in one way anyway, right. Service

planners will benefit, and then they can invest more money. People, Behaviour Therapy Team will benefit as well because it will mean more investment into the team.” (John, nurse)

In John’s opinion, the RCT will benefit a variety of stakeholders. He suggests that service users will benefit, but that investors will be able to invest more money on a service that has been evaluated. Effectively, this represents benefits at a strategic, management level:

Extract 4d.30 – “the organisation perhaps benefits if they’re funding an expensive service that is very effective then you know things need to change so I guess the organisation benefits. The *team* could benefit, *ultimately* hopefully, clients would benefit...so in the long run some people who do benefit ...but at a cost perhaps to some others.” (Louise, nurse)

Louise approaches the subject from a top-down perspective. She suggests that the strategic organisations involved in service delivery will benefit first. This may cascade into the intervention team themselves, and finally the service users may also benefit. However, she also highlights another important outcome; the potential cost of the RCT, suggesting that there is a conflict of interest. This is expressed more explicitly in the following extract:

Extract 4d.31 – “Hopefully...the client [will benefit], but...again the question is who do we run the service for, the people who provide it or the people who receive it?” (Nicholas, social care professional)

Nicholas suggests that there is a conflict of interest between service providers and service users regarding research outcomes. This conflict is difficult to reconcile if financial resources are perceived to be lacking. The following extract suggests the importance of timescale, when considering the benefits:

Extract 4d.32 – “In the time-scale of *that research*, it probably is not gonna make any difference or possibly an adverse for the ones that don’t, but I mean you’re looking to...in the long run if you find this *is* effective,

then perhaps you'll increase the service, and more people will get it so it could have a *long* term good outcome for them [...] but if you can't *prove* it's useful, you're not gonna get any money to do it." (Christine, nurse)

Christine also refers to the potential costs of the RCT, as some participants may not receive timely intervention from a specialist team. However, she seems to believe that long-term benefits from the trial may help some service users in the future, depending on the outcome of the trial. This therefore suggests another conflict, between short-term and long-term benefits from research outcomes.

May expresses a similar view:

Extract 4d.33 – "I think the behaviour team benefits from being recognised that they are a good resource, they will benefit. Ultimately...it will be recognised that it will be for the clients but I don't think the full benefit is the clients here, for *now*." (May, psychiatric nurse)

If anything, the extracts presented above highlight the complicated process of translating research knowledge into potential benefit in practice. In the eyes of the local stakeholder, the practical benefit is integral to the success of a research process. However, the time-scale of seeing potential benefits arise makes it difficult for stakeholders to appreciate potential benefits that may arise from the RCT. However, it was Greg who offered the most comprehensive explanation of the potential outcomes and benefits that may arise from the RCT:

Extract 4d.34 – "If it led to more resources for the Behaviour Therapy Team and not at the expense of other areas then that could...would have to be good for *everyone* because I'm sure the Behaviour Therapy Team do 'good' rather than make things worse so if they were given a boost in some way it could only be a good thing. So the Behaviour Therapy Team patients could benefit from it in that way. And if it showed the Behaviour Therapy Team not to be particularly effective then that's gonna be a problem for them [laughs], and if they were to go by the wayside then that would be a problem for the patients as I don't imagine they would necessarily be replaced but the money might just disappear." (Greg, clinician)



Greg covers many aspects of potential research outcome here. The perception of limited financial resources seems to dominate his opinions. His comments about the RCT providing evidence for more resources are tempered by his observation that resources may be taken from elsewhere. He also highlights that potential benefit to the intervention team is dependent upon the outcome of the research. Overall, although interviewees had various conceptions about the potential beneficiaries, most did suggest that there would be some benefits to the RCT. The following comment provides an exception:

Extract 4d.35 – “I’m not sure anybody does...Erm you can’t...presume...ooh I’ll tell you who benefits, the research team, they get the money.” (Janice, professional service manager)

Janice had a negative attitude towards the trial, and this is evident within this extract. However, in general professionals appeared to have positive attitudes towards research, and even to the outcomes of the trial. Professionals were aware of the important ties between research and resource allocation which shall now be discussed.

#### **4d.3 The work environment**

Professionals’ work environment appeared to be delineated along defined routes for accessing help and support for service users when needed. Professionals, like paid carers, would usually begin by looking within the team itself. Difficulties that arose with particular service users could be shared:

Extract 4d.36 – “obviously we look within our own peer...group because we have the supervision within our own peer...other co-coordinators, and we have our meetings as well so sometimes we discuss difficult cases. [...] all team members sort of get involved with ideas and at the end of it at *least* you know you feel as if you’re not on your own, you’ve got ideas to try.” (May, nurse)

A professional peer group could be a helpful and highly valued activity. I interpret May's comments as showing an attempt to solve a problem. The problem needs to be solved using the resources that are available within the team. The root cause of a service user's difficulties can be discussed with others. This comment highlights the concept of 'trying ideas'. This appears to be an important way in which people seek help for service users. The input, support and ideas from others are needed to find solutions, almost through a process of trial and error. Hannah, a social care professional, echoes this:

Extract 4d.37 – “when I refer a service user I have an idea whether they will respond or get any benefit so I think that's a risk worth taking because if it's not tried then we've got no idea whether somebody's quality of life could be improved or not and it...*maybe* that it's *not* improved but its...you've gotta try it.” (Hannah, social care professional)

Hannah seems to share the belief that ideas and solutions need to be found through perseverance. In particular, she states that although the proposed solution may not work, it is worth trying. This is another variation of the trial and error process described by family and paid carers.

Again, the theme of lacking resources in the work environment was a strong contextual factor in all of the interviews. For some, intellectual disability services were believed to be in difficulty because of the financial motivations behind the decision making:

Extract 4d.38 – “I used to once upon a time think it was a needs-led service, and occasionally people could have a few aspirations which would be really nice, but now I just find that'...it's a money-led service. [...] we just seem to go round in circles all the time... new ideas come up, research is done...money matters take over, research is lost and we go back again and it's just a never-ending circle” (Natalie, social care professional)

And this lack of resources would possibly make it difficult for research to fulfil its potential in this environment. Natalie sees this way of working as time-

consuming and ultimately unproductive. Research appears unable to break the chain within this challenging context. This indicates her feelings that the culture of lacking financial resources is embedded within the intellectual disability community. This potentially makes it difficult to provide individualised care:

Extract 4d.39 – “With average caseloads of twenty to thirty clients it’s very difficult for us to actually take that time out of activities for other clients, to actually spend more time with one individual.” (Mark, nurse)

Mark mentions the difficulty in having to manage a caseload. His comments provide further evidence that the professional services are resource-limited. His comments evoke a feeling of powerlessness when he describes that it is difficult for him and his colleagues to spend the time catering for the needs of certain individuals. A more specific opinion regarding resources is shown in the following extract, where Catherine offers her explanation of the mechanics behind NHS funding:

Extract 4d.40 – “I think kinda the culture within the NHS is turning much more into kind of a business style, particularly us as a Foundation thing now, so we need to sitting and saying you know ‘this is the reason why we’re doing that’” (Catherine, professional therapist)

Catherine’s comments do not seem to be particularly negative or accusatory. Her opinion seems to indicate her feeling that times are changing; that the NHS was run less like a business in the past. Interestingly, she refers to the fact that this particular NHS Trust has recently become an NHS Foundation Trust. The implications of this mean that the Foundation Trust receives a certain amount of autonomy from the Government. This autonomy relates directly to funding issues, such as the provision of resources (see Chapter 2 for more information about NHS Foundation Trusts). The autonomy from the Government should indicate that decisions about the provision of resources are made on a more local level. Indeed, one senior manager demonstrates some autonomy with regards to future investments in the following extract:

Extract 4d.41 – “I’d need to get...sit down in this office in this room here, with...with the rest of the senior management [...] I for one will be asking our local commissioners to help being invested in that model” (Oliver, professional service manager)

Oliver indicates that he is able to discuss the provision of services with commissioners. This shows that Oliver has more connection with funding sources than many of the other interviewees. In this instance, the commissioners are responsible for providing the funding for services, especially those that have been rigorously evaluated in research. The above quote indicates that money and investment is available, and that there is a pathway by which this investment can be accessed. Another senior manager corroborates this:

Extract 4d.42 – “I *commission* services for learning disabled people. I mean over *all* services as well as agreeing to specific service provision. So I have ideas about new services, short-break services, I’ve just started a community service volunteer independent living service. Then I also have complete control over financial commitments in terms of individual needs [...] I manage a £12 million budget.” (Janice, professional service manager)

Senior managers such as Janice and Oliver indicate that resources and investment in services for people with intellectual disability are available, and that information about resource provision is available to people working within these services.

Resources may be in short supply, or managed inappropriately – but services exist. It is important to discuss how these services work in order to illustrate how research and RCTs must function within this environment. The following quote indicates one important principle for working within a multi-disciplinary environment. Here, David is describing the Behaviour Therapy Team, and how he has accessed them in the past before the trial began:

Extract 4d.43 – “they’re a valuable part of our *team*, you know we all work together in multi-disciplinary team and they certainly have been beneficial over the years.” (David, social care professional)

The principles of mutual co-operation and teamwork are immediately evident from David’s comment. This appears to exist within a complicated structure; a multi-disciplinary team of various professionals working together. Other interviewees also alluded to this, in describing the referral pattern to the Behaviour Therapy Team:

Extract 4d.44 – “it goes to a community team, and then the community team decide whether they, the person needs behaviour input, so social workers, community nurses, psychiatrists, it’s the whole multi-disciplinary team.” (Marie, nurse)

The concept of the multi-disciplinary team arises often in these interviews. Marie is describing the referral process to the specialist intervention team where she works. Social care teams are required to work closely with members from health teams, and she also mentions some of the job roles. Such a resource poor, team-based environment has its own challenges:

Extract 4d.45 – “Staff morale, motivation is really important because we work with quite a *hard* client group, and I mean you need to be motivated to be able to improve their lives.” (Andrea, nurse)

Andrea claims that people with intellectual disability are a ‘hard client group’ and she mentions the need for high morale and motivation. I interpreted this comment to mean that it is difficult for carers to achieve outcomes for service users. This could possibly be due to the disadvantages that these people already face in society. Natalie, in the following quote appears to be suffering from a lack of morale:

Extract 4d.46 – “I think people would still slip through the net...between services, we’re not very good really as a [laughs] as a service.” (Natalie, social care professional)

Comments such as Natalie's are interesting but they are not common within the interviews. I have interpreted this in a light-hearted way, and she laughs as she makes the comment. However, I do believe that there is an element of seriousness in what she says, indicating a lack of confidence in her work and within her working organisation. This is in stark contrast to Mary's beliefs regarding her role:

Extract 4d.47 – "I don't *live* in South East Essex. I choose to work here you know, I travel a round journey is probably about 75-80 miles a day and that's without the journeys I do *while* I'm working, that's without my travelling round. I *chose* to come here because there was a Behaviour Therapy Team. That speaks for itself, I *do* believe it works, I know it works, I believe that there should be, you know, more access to services like ours" (Mary, nurse)

Mary appears to be very proud of her role and what she is able to achieve for the service users. She highlights how the service she works for is not available elsewhere, providing evidence that access to specialist services may be problematic in other geographical areas. Financial resources may be limited, but outcomes can be achieved through teamwork, experience and motivation. Mary appears to express a certain pride in her role and the conviction that she is doing something worthwhile. James also indicates pride in his role:

Extract 4d.48 – "they know who I am, they know what the carers' link worker is, they know what they *do*, they know if they've got a problem specific to their caring role they come to me, as opposed to *any* of the social workers. I mean, we can all do the work but it happens to be the hat I wear apart from my general role" (James, social care professional)

The source of James's pride seems to be due to the fact that he has found a niche within his working environment. He is defining his specialist role within the multi-disciplinary team. This is another principle that I wish to highlight in this section: the need for clearly defined roles within the team. These subtle definitions may be important for keeping people motivated and highly

functioning. Sayeed describes this need for these definitions in the following extract:

Extract 4d.49 – “I felt that the *skills* of the nurses have not been openly utilised...they have really been equipped and been given time to specialise in this kind of work, because I don’t always...sometimes [it is] very, very difficult to...see [how] nursing work differs from a social worker’s work, they’re quite overlapping and not particularly highly specialised.” (Sayeed, clinician)

Sayeed appears to be referring to the fact that people within the multi-disciplinary team need to adopt specialist roles. This would prevent two different disciplines doing the same work, theoretically saving resources. As described in Chapter 2, the multi-disciplinary team includes staff from health and social care. Sayeed claims that the roles of the psychiatric nurse and the social worker need to be more clearly delineated. I have interpreted this to mean that a multi-disciplinary team needs to include people who have clearly defined roles. In his opinion, the psychiatric nurses should be specialised in delivering psychiatric care for people with intellectual disability. Within this, the provision and placement of specialist services such as the Behaviour Therapy Team was not always universally agreed:

Extract 4d.50 – “I don’t like the separation of a specialist, of the Mansell Report, just to clarify the Mansell Report said very much you should have a strong infrastructure in local generic services. Umm and then that you’d bring in the support so it’s not that they’re integrated, but they come and work *with* the local service in the skill-teach model and then withdraw.” (Elaine, professional therapist)

I interpreted Elaine’s comments to mean that she believes that expertise should be distributed around the teams so that skills can be shared across professional boundaries. This way the specialists could share their knowledge with other members of the team. Whatever the model and however it is implemented, it would appear that the whole intellectual disability service employed a series of complex multi-disciplinary teams including specialist and more generic services.

There were constant challenges in getting the teams to function optimally to preserve resources, but team members appeared unanimous in their vision to create a better future for their client base.

#### **4d.4 Service maintenance and development**

In many professionals' minds, research was conceptualised within the work environment as a way of maintaining and improving standards. In this sense, professionals tended to take a wide perspective on the need for research. When asked, professionals were keen to ensure that the quality of their services was being maintained, especially in the light of limited resources:

Extract 4d.51 – “I think we’ve got a duty really to make well that you know the powers that be have got a duty to make sure that their money is well spent, and that you know the service is providing the thing they set out to provide, yeah.” (Mary, nurse)

Extract 4d.52 – “I don’t think in the NHS we have had a history of assessing outcome *enough*, and we need to get far more...far more *thorough* for both you know, the best use of public money as well as...to provide the best possible support services.” (Alice, professional therapist)

Mary appears to regard the maintenance and monitoring of standards within services for people with intellectual disability as a duty. She links this duty to higher organisational structures and to the provision and availability of financial resources. Alice also implies a sense of duty in relation to agencies such as the NHS, her employer. However, this idea of monitoring services was sometimes seen as a Sword of Damocles:

Extract 4d.53 – “it keeps people on their toes, and hopefully it shows that...I suppose that a service *isn’t* achieving what it should be, changes can be made and hopefully for the better because at the end of the day if it’s *not* achieving what it should be we’re only failing the people that we’re



supposed to be serving so... that's the best way to do it." (David, social care professional)

Again, the sense of duty to service users arises. David refers to the need for services to be 'kept on their toes' through monitoring of quality standards, and often research was seen within this context. In the following extract, James discusses his own experiences of working within a professional team and being monitored:

Extract 4d.54 – "the ones who are actually receiving the service are the ones who tell us whether we're doing it right or not. Err...we obviously, you know, we're assessed by CSCI as well and they keep an eye on us to make sure we're doing the right thing." (James, social care professional)

James draws attention to different methods of monitoring. He thinks service user perspectives provide useful feedback. He then refers to the Commission for Social Care Inspection (CSCI), which was an organisation that inspected care homes and care services for people with intellectual disability. The presence of such organisations and familiarity with service monitoring may affect perceptions about research and service development. The need to provide consistent and good quality services for people with intellectual disability was linked to the need to assess and monitor the progress of the services. This was seen as one of the major functions of research into intellectual disability services. Other interviewees often did discuss research in terms of service development, and some referred to the principles of evidence-based practice:

Extract 4d.55 – "without research and evidence...we're quite likely gonna shoot ourselves in the foot, we're going to say that we're a really important service, and then have no way of backing that up and saying well 'actually research has shown they have this sort of input and has had immediate results that can be seen' and without that we just gonna say 'well I think we're doing a good job', and you can't support it apart from your own experiences so I think it's really important and it's the only

way that you can evolve and move forward and develop as a service.”  
(Catherine, professional therapist)

This extract differs from those presented previously in that it discusses the importance of research to support the work of professional services, rather than merely to monitor the service standards. Catherine touches on two important points here; she introduces the difference between subjective and objective opinion, and she suggests that research can provide objective support for demonstrating the value of a service. In turn, evidence from research can support the work of professionals, providing them with some sense of service validation. She was not the only professional participant to express views such as these:

Extract 4d.56 – “we need research because research informs theory and theory is what we use to back up everything that we do in working with some of the country’s most vulnerable people...I just think it’s so useful because and then theory informs research and it’s an ever going, it’s a life cycle which is just so positive and practices can only be made better...by that.” (Natalie, social care professional)

Immediately noticeable within this extract is the overwhelmingly positive attitude that Natalie has towards research. Like Catherine, she also discusses the need for research to support improvements and developments within professional services. She refers to the importance of theory, which underpins her work within the intellectual disability services. Theory is linked to practice, and in this sense research is seen to inform theory. The principles of evidence-based practice with regard to research and service development are discussed by Rebecca:

Extract 4d.57 – “I think in today’s...age, it’s important to work from evidence base so research is our only way of getting that evidence base to justify what we doing and the way we’re doing it, and to make sure that we’re using the most effective means possible in supporting people.”  
(Rebecca, nurse)

Rebecca was one of the few interviewees to link research to evidence-based practice directly. She emphasises the importance of justifying her work and proving her worth, in order to provide a quality service. Catherine discusses evidence-based practice in the following extract:

Extract 4d.58 – “I think it’s vital to our work and its core to our OT philosophy that your work is evidence-based. Erm, but...it’s often difficult to find because at learning disability, there’s little evidence and therefore we often taking evidence maybe from mental health or from other areas and then *adapting* it across to LD rather than it being LD specific.”  
(Catherine, professional therapist)

She states that the principles of evidence-based practice are fundamental to her profession. She has concerns about adapting evidence from other areas of mental health because they may lack relevance for people with intellectual disability. She seems to think that there is a lack of research, and a need for research. The need to provide evidence was perceived to be related to the Government and other such organisations:

Extract 4d.59 – “there’s a massive drive from the Government to actually *prove* what you are doing and what’s the worth, I mean one of the things that is favoured now in people with learning disabilities are coming into it is Cognitive Behavioural Therapy, because its short, and you can show you’ve either succeeded or you haven’t.” (Nicholas, social care professional)

Nicholas appears to have a positive attitude towards research and evidence-based practice. Indirectly he alludes to the pressure of resources when he talks about the benefits of Cognitive Behavioural Therapy. Favourable opinions of evidence-based practice were not universal:

Extract 4d.60 – “it’s such a *shame* that in this age, this 21st Century that you have to prove that you know. I know it is something we have to do but it’s so sad that you have to *prove* that something *works* you know, there must be another way of doing it, I don’t know. That you have to

prove that something works, why can't we actually look at proving that we can do something *better* instead? That we can work *better*?" (May, nurse)

May appears sceptical of the concept of proof in this context, through seeing it as a sign of the times. She contrasts the need for proof with the need for improvement. Improvement was a common theme throughout the interviews, both in terms of general research and in terms of service development.

Professionals' perceptions of research appeared to be related both to opinions about service monitoring activities (or maintenance), and to service development with evidence-based practice. On both counts, opinions about research were closely linked to opinions about the provision of resources. Many carers and professionals believed that research, monitoring and evaluation were necessary in order to maintain the quality of the service, and were useful for preventing stagnation and for encouraging improvement. This was perceived to be a sign of the times.

#### **4d.5 Perceptions of the trial**

As many professionals understood the context in which the trial existed, there may have been an expectation that they would well understand the trial. In fact, professionals varied greatly in their knowledge and understanding of research concepts. On a basic level, nearly all had a conception of what was meant by the word 'trial' in this context:

Extract 4d.61 – "'Trial', test, like a pilot study to a certain extent, a trial is like a test...like a dummy run at something I suppose." (Carla, nurse)

Extract 4d.62 – "a trial is something that is just...I dunno a temporary...thing just a trial run really, yeah a practice run." (Mary, behaviour nurse)

However, interviewees who had previous experience with research were often able to elaborate further on what they thought the trial to represent:

Extract 4d.63 – “It means that you are allocating people to groups without reference *necessarily* to any one bias, be it age, gender, geographical locality, marital status, sexual orientation.” (Elaine, professional therapist)

Comments such as this were nonetheless in the minority, this interviewee had a scientific background and she was therefore mindful of how the method was used in this context. Beyond terminology, professionals appeared to have a basic understanding of the RCT method in most cases. As with all of the stakeholders, this was dependent upon understanding of the rationale behind the study, and of the reasons underpinning the procedure:

Extract 4d.64 – “I’ve got a basic understanding of it. I’m aware that they’re trying to look at the effectiveness of the service and whether what they do is *valuable* to the clients, improving clients’ lives.” (Andrea, nurse)

Extract 4d.65 – “I’m *presuming* to find out if there actually is value in a specific Behaviour Therapy Team is actually effective or not.” (James, social care professional)

Extract 4d.66 – “they want to find out whether the behaviour therapy service is *effective* compared with people who are not being referred to the behaviour therapists’ team.” (Julie, nurse)

These quotes from nurses and social workers are remarkably similar. All three extracts relate to evaluating the effectiveness of the intervention service. Within this framework, many interviewees were able to describe the reasoning behind some of the methodological processes that underpinned randomisation.

Extract 4d.67 – “So you don’t influence the research to the end that you might want it to be, or erm...so you *can* say that it’s like a blind study and the fact that you don’t know the people that are going *into* it, which

makes it more...*more* of a true study, more of a true research.” (Charlotte, nurse)

The extract above shows Charlotte’s response to a question about her perceptions of the reasons underlying random allocation. She mentions the need to reduce human factors by implementing a blind allocation procedure, which she sees as a way to improve the objectivity of the research. Others made similar comments:

Extract 4d.68 – “makes it better and then they’re not composing the situation you know, then it is chosen randomly” (Andy, nurse)

Extract 4d.69 – “if you’re actually selecting people for what group they’re going in, it doesn’t matter who you are there’s got to be a bias.” (James, social care professional)

Both Andy and James describe the problem of systematic bias, and the dangers of introducing human influence into research. Random allocation was in these cases believed to be a way of reducing systematic biases. Other professionals related instead to the idea of randomisation providing equal opportunities for participants:

Extract 4d.70 – “I like the fact that it’s random and obviously each person has an equal chance of being in Group 1 or 2, there’s no criteria for what group people go in, so it’s just a really equal, everyone’s got the same equal opportunities.” (Carla, nurse)

Aside from avoiding bias and promoting equal opportunity, others recounted the need to make comparisons between groups:

Extract 4d.71 – “I actually think it’s quite a good situation because that’s how you’re gonna find if there *are* any...differences from team to team.” (Angela, support worker)

Angela shows a positive attitude towards the RCT procedure because she identifies the need for comparisons in order to ensure that the service evaluation is performed properly. Amongst some professionals, there was a belief in the necessity of comparison groups in order to perform an evaluation:

Extract 4d.72 – “I quite understand that without *doing* it, we wouldn’t know the *result*. It’s one of those things that I believe has to be *done*, and it has to be done in order to get some answers” (Oliver, professional service manager)

This recognition of the necessity to provide a comparison group appeared to increase acceptance of the trial. Some referred to this method as essential for this purpose:

Extract 4d.73 – “Well there’s nothing to think about, randomised controlled trials are important, important to find out and...how effective the treatment that is helping people. Without *that* obviously the kind of conclusions that we may...might make, not be correct.” (Sayeed, clinician)

Sayeed relates RCT procedure to treatment efficacy, and appears to favour RCTs. He implies their usefulness for research, as the gold standard for clinical effectiveness. His medical training undoubtedly affected his understanding of clinical research procedures. Another clinician, Greg, discusses RCTs in contrast with alternative approaches:

Extract 4d.74 – “well that’s supposed to be the gold standard...you could do a kind of lower...level study in a way where it’s much more qualitative but it wouldn’t have as much power the result maybe and huge amounts of bias, possibly to the extent that it wouldn’t be taken seriously, so the randomisation does give it a bit of credibility” (Greg, clinician)

Greg suggests that randomisation has the potential to reduce bias. He believes that this credibility is needed to create believable results for audiences. However, not everyone appeared to hold the same view:

Extract 4d.75 – “So randomised research you could say that it’s more like a clinical thing, more of a medical thing [laughs] so it’s difficult to do a randomised type of research on the...really this is a social group, people with learning disability is a social group.” (Julie, nurse)

Julie discusses why RCTs are uncommon in intellectual disability; she is a nurse with a clinical background but appears to see intellectual disability primarily as a social population rather than as a clinical population. Janice presents her view from the perspective of someone who works in social services:

Extract 4d.76 – “I think it’s fundamentally flawed because it depends on your local learning disability service, and also how that relates to your local behaviour therapy service. And if they are very different then there isn’t a true comparison to be made [...] this was a conventional approach to an unconventional area.” (Janice, professional service manager)

Here, she highlights what she believes to be one of the difficulties in conducting an RCT in this particular context. She suggests that the infrastructure of the service may make it difficult to provide appropriate comparison groups, thus endangering the rigour of the research. Hannah makes a similar statement:

Extract 4d.77 – “on a *quantitative* level I mean I don’t know that it’s actually *measurable*, on a qualitative level then *yeah* I mean but that’s gotta be individuals...individually assessed. [...] It might not *show* the benefits, it might just show certain people have...had the program at whatever ‘x’ cost and that the results have been miniscule on a quantitative level, but if the carers feel that it’s been of benefit then I think that’s immeasurable.” (Hannah, social care professional)

Hannah refers specifically to this particular RCT. However, in more general terms, she appears to show distrust for reductionism and for using quantitative methods to evaluate this kind of intervention, which parallels the views of many of the paid carers. Even if professionals were able to empathise with the trial procedure, they may not necessarily accept it wholeheartedly:



Extract 4d.78 – “I understand why it’s done I just kinda think it’s a bit horrible.” (Andrea, nurse)

This problem may stem from the fact that service users are perceived as helpless to whether they get randomised to one group or not. Professionals did have misgivings about the ethics of a complex methodological procedure that would be difficult for service users to understand:

Extract 4d.79 – “I think one of the *ethical* problems is whether all the people with learning disabilities understood...I mean if I was selecting for a clinical trial I may understand that I may be given a medication, I may have a placebo and not know, and I would have the ability to decide you know whether I was to take part.” (Nicholas, social care professional)

Extract 4d.80 – “I don't think a lot of our clients could ever understand the implications of something like this.” (Rebecca, nurse)

Nicholas relates to a problem which is specific to conducting RCTs with people who have intellectual disability. He relates to the participants’ ability to understand this potentially complex information. Rebecca doubts the service users’ abilities to understand the RCT. A minority of professional interviewees did mention the possibility of using more inclusive research approaches with people with intellectual disability:

Extract 4d.81 – “We *did* talk in the past about doing Action Research with people with a learning disability which *sounded* a good way to go, but I’ve never actually been involved in it. [...] Where you start off with a group and you’re actually looking about planning what you want to do together, and then ask the researcher things...service users actually having a lot more *control* over the research, taking much more a part in it, *guiding* the process.” (Christine, nurse)

This extract discusses the possibilities of Action Research approaches, which enable the service user to define the parameters of the research and to take a more active role throughout the lifetime of the project. As Elaine mentions in

the following extract, there may be scope for combining alternative approaches such as this with more traditional clinical research:

Extract 4d.82 – “I mean yeah I think we need both types, we need the research that is clinically related to address clinical questions. I think that there’s always gonna be a *role* for that kind of research, but we should also be looking at service users being much more involved right from beginning, from submitting the proposal and actually making sure that it is reflecting what *they* want to know.” (Elaine, professional therapist)

#### **4d.6 Randomisation preferences**

As described in the interviews with carers and service users, a common problem related to preferences for allocation to the intervention group above the control group. These preferences were also described by the professionals, especially regarding those service users who were considered to be in the direst need of intervention, those who would be most likely to be referred to professional services in the first instance:

Extract 4d.83 – “for people in crisis it must be very hard to have to wait and I *am* aware of somebody who was referred to the team whose mother was very upset because she felt quite desperate for help and I think she did *get* it but initially she was told that of course we couldn’t guarantee that her son would be seen and was very upset about it.”  
(Louise, nurse)

This passage suggests unsurprisingly that crisis situations can increase allocation preferences. The more desperate a participant is to receive help, the greater their preference to be allocated to the intervention group. Janice expresses her preferences:

Extract 4d.84 – “they’re already in enough trouble without being allocated to some sort of random ‘yes we’ll have this one and no we won’t have that one’” (Janice, professional service manager)

Janice emphasises the vulnerability of people with intellectual disability. This may reflect a protective attitude towards service users. As she says, the service users who participated in the REBILD trial may have other problems. Her preferences for the intervention group over the control group are obvious, and this pattern was repeated for almost every participant interviewed. Within this particular RCT, these preferences appeared to be widespread and deep rooted. Mary summarises the conflict between preferences for allocation and the demands of evidence-based practice:

Extract 4d.85 – “you know [if] somebody said to me ‘would you rather wait six months or more and go to a service that is going to be really effective, or go directly to a service that we really don’t know *how* that service works [...] if you had your sensible head on I think you would say ‘ooh look I would rather *know* that this service is really, really good’. Having said that...if you’re *living* with somebody who’s displaying challenging behaviour, if you’re trying to give a *service* to somebody, if somebody is in *crisis* then...you know you want it *now*.” (Mary, behaviour therapist)

This extract highlights the contradiction between providing short-term intervention for a crisis situation, and providing a long-term evaluation of the effectiveness of a service. She appears to suggest that validation of effectiveness is objectively valuable, but access to services is considered more important because of participants’ subjective preferences. Individuals who showed no preferences, or who may be said to hold positions of personal equipoise (i.e., describing a position of uncertainty about which allocation group was best) were uncommon. However, the following extract may demonstrate this:

Extract 4d.86 – “possibility people might be missing out if they didn’t see the Behaviour Therapy Team during that time. It all depends on how good the Behaviour Therapy Team is, so if it was really good then it would be a shame for the people in the control group personally in the short term. Umm if they weren’t much cop then it wouldn’t really matter too much.” (Greg, clinician)

Greg suggests that the quality of intervention underpins the fairness of randomisation. This position is as close as any of the participants came to expressing a position of personal equipoise. Even within this extract, Greg does seem to express some personal preference when he describes the problem of participants 'missing out' on the intervention service. This essentially relates to the central concern of accessing services and interventions:

Extract 4d.87 – “they're missing out on that service aren't they, and they've obviously been referred to behaviour therapy for a reason and...and that because of the research they're gonna be kind of missing out.” (Andrea, nurse)

Andrea also describes participants as 'missing out' in the context of preferences for allocation group; presumably she refers to participants randomised to the control group. She emphasises an important point, that the participants in the REBILD trial were all people who came to the attention of intellectual disability services because they were perceived to need help or intervention at that time, as shown in Sub-chapters 4a and 4b. Hannah agrees, and highlights some of the potential ethical considerations that need to be considered when undertaking such an RCT:

Extract 4d.88 – “Well I think one of the problems is that if somebody has been *referred* to the Behavioural Therapy Team, and they're not getting the help that they desperately require, its potentially abusive...And it's also leading the carers up the garden path, if the carer thinks 'oh at last I'm going to get some help' and then they actually in fact *don't* get any help at all, but it's actually quite sadistic.” (Hannah, social care professional)

Hannah refers to the need of a service user or carer to access an intervention. Within this context, she appears to show negative attitudes towards the RCT. She describes the problem of 'false promises', with carers receiving no help. This attitude is again likely to stem from the perceived lack of resources.

Professional participants actually tended to be more vehement about this particular issue than other stakeholders:

Extract 4d.89 – “there are situations where people have terrible behaviour problems and I needed the information there and then really, to help.” (Carla, nurse)

Extract 4d.90 – “by randomising the cases, you’re stopping us from using the *service* that we really badly need, because we’re not just referring for the sake of referring, we refer because they are at, you know desperation, and we’ve tried everything we can. And where do we go then? You know, we’re stuck [...] it’s *very* frustrating when you have to wait six months when you’re really at breaking point already, and you just can’t afford to do that.” (May, nurse)

The crisis situations described by Carla and May do not sit comfortably alongside the need to randomise participants for the sake of methodological soundness. In these cases, the nurses describe situations where randomisation prevented them from accessing help. This highlights the complicated interaction with traditional models of service delivery that exist in the absence of an RCT. Two further participants describe the difficulties of adjusting to this change:

Extract 4d.91 – “It’s *very* complicated because obviously people are being chosen randomly and they’re not through the usual process and these people are sort of highly, highly complex individuals that need that amount of counselling and they’ve got behaviour input at the moment in their local areas and you know, they could do with it now.” (David, social care professional)

Extract 4d.92 – “you need a control group for comparing it against and the only fair way of doing that is to randomise it...But yeah it has just been frustrating with lots of ours being under *control group* rather than actually in the trial.” (Catherine, professional therapist)

Like others, David mentions the complexity of the problems of individuals within the RCT. Catherine appears to accept randomisation, but describes the negative consequences of it. It is interesting to note her terminology here. She appears to consider only those participants who were randomised to the intervention group as 'trial' participants. Rebecca describes a real-world situation arising in response to the RCT:

Extract 4d.93 – “those that ended up going out and getting Treatment As Usual basically got no treatment, because if we'd already decided that we couldn't cope with them then so we're referring them on to a specialist service, and they're saying 'you look after 'em for another six months' we're jeopardising their placement, we were putting *them* at risk, we were putting other people at risk.” (Rebecca, nurse)

In this extract Rebecca describes how some of the participants in the control group for the REBILD trial were treated. It appears as though the community learning disability service had exhausted options for certain participants. In the absence of intervention allocation, participants in the control group received no input. This highlights the problem of finding suitable comparison groups in pragmatic RCTs. Overall, she demonstrates a negative attitude towards randomisation based upon practical ethical concerns. She concludes in an ambivalent manner:

Extract 4d.94 – “it's just...been a couple of years of *us* feeling unsupported but yeah, I can see that research has to be done some way.” (Rebecca, nurse)

REBILD refined the referral patterns, so that only those participants who were willing to take part in the trial were able to get behaviour therapy. Professionals often felt the need for this service once they had exhausted other avenues:

Extract 4d.95 – “it's our *nurses* that normally do the referrals rather than *us* and they're very skilled and if they can't manage it there's normally a good reason why and that's why you need the more specific influence.” (Catherine, professional therapist)

Here Catherine is keen to state her confidence in other members of her own nursing team. However, she iterates when and why a specific influence would be required in cases when the nursing team would be unable to provide adequate support. Rebecca also says this:

Extract 4d.96 – “we lost our specialist knowledge of and then couldn't get access to the teams...again.” (Rebecca, nurse)

Rebecca reveals a need for specialist input and skills for certain difficult situations. It was difficult for Rebecca's team to access the Behaviour Therapy Team because of restricted access within the REBILD trial. This has a knock-on effect for certain professionals to take a lead role on certain aspects of care:

Extract 4d.97 – “if somebody *does* get taken on by the behaviour therapy service, we say that as a relaxation of *our* role because we can then move I suppose further back to the sidelines whilst they assess the person's behaviour, we may still look at other areas involving that person, health needs, any other needs that aren't being addressed as part of the Behaviour Therapy Team's role, but who takes the lead dominance, who's got the lead role in actually working with the individual?” (Mark, nurse)

This relaxation of roles that Mark refers to is probably again a consequence of lacking financial resources. As described previously, people who work within the services need to use their time wisely; they need to avoid doing the same work as other people. This suggests a certain fluidity in roles that is necessary in this context. This is more obvious in the following extract:

Extract 4d.98 – “I think we should be the gate-keeper and if we can't do the work, if we have exhausted our resources [...] Otherwise if its open referrals you can imagine they end up doing a bit of the work that we do isn't it? What a waste of that resource.” (May, nurse)

May seems to view the need for specialist services such as the Behaviour Therapy Team as a backup to the regular work that she does. The importance

of employing resources wisely comes across here, and within this environment it is easy to see how allocation preferences arise so frequently.

#### 4d.7 RCT safeguarding

The various problems that have been identified regarding to the trial relate to the difficulty of understanding the procedure and accessing a valued service. The latter relates to the perceived inflexibility of RCT method, and to how this interacts with the changing needs of the service users, carers and professionals involved. In order to minimise the ethical problems associated with these practical difficulties, interviewees often emphasised the need for appropriate safeguards. One such way was to ensure access to other services for the duration of the RCT:

Extract 4d.99 – “I know for a fact that they weren’t left without *anything* at all, they still had their community services, they had their nurses, they had their OTs, speech and language, and they had their consultants.”  
(Mary, behaviour therapist)

Mary’s chief concern in this extract is that participants should not be left completely without help. Rebecca describes how the presence of alternative services in this particular geographical area made her feel better about the RCT:

Extract 4d.100 – “I think it could've been worse than it was if we didn't have the Behavioural Advisory Team that we then went to, and I realised that that kinda sabotaged some of this to an extent *but* from our perspective we needed that support and we needed it quickly and so if we couldn't get it from one place we went to another.” (Rebecca, nurse)

The Behaviour Advisory Team was a similar intervention to that being tested in the REBILD trial (a full description is provided in Chapter 2; Section 2.1.5). Rebecca admits that seeking out help from alternative sources may potentially affect the RCT. However, she places the needs of participants above methodological demands.



Another safeguard that eased professionals' suspicions was an assurance that participants would eventually be offered the relevant help and support, following completion of the RCT:

Extract 4d.101 – “I would quite like the guarantee that once the trial or research was over then they actually be put back *in* to the mainstream or *back in* to the people who go to behaviour therapy, specific to LD. [...] I don't have difficulty with it as long as there's safeguards.” (James, social care professional)

James appears concerned that trial participants may not receive any support. He wants assurance that participants will receive services after the RCT is complete. Similar opinions were shared by other professionals who were interviewed:

Extract 4d.102 – “depending on the results of this, I really think that we *might* have to revisit...the other group if...to offer them that service again. If it proves that this service with the Behaviour Therapy Team had better outcomes.” (Oliver, professional service manager)

Extract 4d.103 – “I think if you're getting strong results earlier on than the six months that showed it had really positive benefits then maybe the time-scale of the trial should be shortened.” (Catherine, professional therapist)

Oliver appears to base the provision of services on the success of the outcomes. Catherine suggests that an early indication of the success of an intervention would necessitate the shortening of the trial. In both extracts, the emphasis is placed upon providing access to appropriate services. However, not all interviewees were convinced that such suggestions were workable in practice:

Extract 4d.104 – “If you could *guarantee* people at the end of the randomised controlled trial that they would quickly receive what they *hadn't* got because of the trial, that might sort of help but of course you can't *do* that because [...] The team wouldn't have the capacity to

suddenly start working with the people who *hadn't* had the service.”  
(Louise, nurse)

These comments relate to the culture of waiting lists and a lack of financial resources. Louise makes an assumption about the resource limitations of the intervention service. She suggests that the service would be unable to provide timely input for all the participants who had been assigned to the control group. This highlights the potential impact of these limitations when discussing appropriate safeguards. If professional stakeholders were aware of potential safeguarding mechanisms, they became less worried about the appropriateness of the trial:

Extract 4d.105 – “I don't think it's a matter of life and death the intervention that they're bringing in because if somebody was very seriously disturbed and their health and safety risk to themselves or others they'd quite likely be in the inpatient...unit so it's not a major problem on this one.” (Greg, clinician)

This extract highlights the view that service structure has a certain degree of capacity, which allows for some flexibility to evaluate services for people with intellectual disability. The need for safeguards alleviated some of the concerns that professionals may have had with the RCT, which means that these safeguards should be outlined and reported right from the beginning of the study wherever possible.

#### **4d.8 Communication**

Professionals were quick to recognise that there were difficulties in conducting any type of research with people with intellectual disability. Unsurprisingly, communication was cited as one of the biggest barriers. Some professionals explained that this was a mutual problem. The researcher and the service user both attempt to communicate, but barriers to understanding exist on both sides:

Extract 4d.106 – “communication is probably the biggest hurdle, which would be the researcher understanding what the...person with learning disabilities [is] saying and the person with learning disabilities trying to understand what the researcher’s trying to say.” (Charlotte, nurse)

Extract 4d.107 – “you get somebody who has very limited language you know and they have all sorts of ways but...and I often write that I’m not *skilled* enough to actually interpret what their actual or secondly I may not have enough time to spend to find out.” (Nicholas, social care professional)

It is significant that Nicholas emphasises his own communication shortcomings. It is interesting to see professionals ascribing deficiencies in communication to themselves, rather than to the service users. Nicholas also relates the problem of communication to the lack of time he has been able to spend with the service user, which may again reflect the lack of resources in the field.

Extract 4d.108 – “you’re gonna have to tailor your communication basically for each single person. Umm, the levels are gonna be different, their understanding.” (Christine, nurse)

Communication problems are highly variable and depend from person to person, from context to context. It is a complex problem implying that a broad set of communication aids should be prepared for every eventuality, and this is difficult in a climate of caseloads and limited financial resources. Andrea links the individuality of communication to the potential of research:

Extract 4d.109 – “the research needs to be aimed in that sort of specific way, with lots of I don’t know, depending on how people communicate, like Makaton or signs and symbols, things like that to encourage people to be aware of what’s going on.” (Andrea, nurse)

Andrea suggests that research should accommodate communication problems. Service users may need encouragement before engaging with research. This

may link to a decreased confidence or learned helplessness for comprehending information. Louise links this with the problem of communication:

Extract 4d.110 – “Yes they can still tell you how they feel, many of them, but whether they understand what’s been asked...I think often people with learning disabilities are quite acquiescent and will give you the answers they think you want.” (Louise, nurse)

Louise highlights how acquiescence can have implications for communication. Acquiescent service users may pretend to understand in order to please, or simply because they do not wish to show that they have not understood. Hannah also discusses this in relation to the environment that service users may grow up in:

Extract 4d.111 – “people with learning disabilities even quite profound learning disabilities have quite often very strong views on what they like and don’t like. I think they can they can be *helped* to give consent...quite often though they don’t know what they’re being asked and people often have learnt to please, especially going through the educational system they know the answer that’s expected and they give an answer.” (Hannah, social care professional)

Hannah links vulnerability with the educational system. She suggests that service users may not answer in accordance with their wishes. This raises concerns about consent and ethics for research with people who have intellectual disability. She seems to place the onus of communication on the carer or professional, who should use appropriate, accessible methods. This is why the importance of encouragement for communication is particularly relevant:

Extract 4d.112 – “stuff that we’re all *trying* to do is user friendly, *more* user friendly you know pictorial, ‘cos then, some people that understand pictorial cues and Makaton and things *could* be involved within the research themselves.” (Marie, nurse)

Extract 4d.113 – “these days there’s so much communication aids isn’t it? we’ve got speech and language therapies, we’ve got you know people who *know* how to communicate with them best. We need to make most, you know best use of those resources to *try*...at least try our best to make sure we communicate what we’re trying to do with them.” (May, nurse)

These extracts highlight the potential of communication aids, which have also been mentioned by paid carers. Interestingly, May’s comments actually contradict the prevailing feeling of lacking resources. Alice’s opinion about the provision of communication support is more representative of the majority view:

Extract 4d.114 – “in an ideal world, if we had...say if we had enough *communication* support for a person, and ideally from childhood, we would then have more communication able *adults* to involve in the research both as participants and as *researchers* themselves even.” (Alice, professional therapist)

Alice suggests that communication problems are due to neglecting communication in childhood, which corroborates some of the views expressed by service users. She suggests that the current state of affairs limits research participation amongst service users. Essentially, long term difficulties in communication pose significant problems to any research:

Extract 4d.115 – “it has *always* been a difficult field because you *do not* have a subjective view of the service user [...] I find it quite difficult to undertake research especially where the service users are...involved.” (Andy, nurse)

This extract relates to the difficulties of conducting research that involves the service user. Andy highlights how communication difficulties can affect research accuracy, as the service user’s viewpoint can be difficult to obtain. The service user’s subjective opinion is considered to be the ideal standard for improving research accuracy. In the following quote, Rebecca has similar concerns about achieving objectivity, this emerges as one of the major

problems that carers and professionals perceive when discussing the difficulties of conducting research in this field.

Extract 4d.116 – “I think must be *amazingly* difficult...essentially because a lot of the subjects of the research can't always advocate on their own *behalf*, haven't got their own views and opinions on the care that's been given to them, and err...it yeah it must be just be communication itself lends to added difficulties, so a lot of the information that's gathered I would imagine comes mainly from the carers, and that's not always gonna be objective.” (Rebecca, nurse)

The principle of objectivity is considered important to maintain the integrity of research; it is a principle that was also mentioned by paid carers. The importance of adequate communication is paramount. Professionals express a desire to accurately represent service user views. Nevertheless, difficulties in communication have still more important implications; communication difficulties preclude difficulties in obtaining informed consent to participate in research.

#### **4d.9 Informed consent**

The process of informed consent is crucially linked to the ethical integrity of a research project. Professionals described that this problem exists beyond research, affecting many decisions that carers and professionals make for service users who lack the capacity to provide informed consent. Louise makes an important point about the consent process:

Extract 4d.117 – “to some degree you know there are always areas in which *any* of us don't know as much as perhaps we *could* know...and our *own* consent isn't *that* informed and yet we make the choices ourselves anyway.” (Louise, nurse)

This opinion suggests that consent and decisions are not always seen to be completely informed. It is important to bear this problem in mind when relating to any opinions about the informed consent process. However, most reflected

on the consent problem as a specific problem for service users, as seen in the following extract:

Extract 4d.118 – “there’s always a question of...consent isn’t it with our clients, whether they truly understand what you are trying to do...and whether you’re getting their true participation or not.” (May, nurse)

This quote outlines the importance of gaining informed consent. She implies that she finds it difficult to ascertain whether a service user has understood sufficiently. She refers to the ‘true participation’, suggesting that participation without consent and understanding is false. Elaine takes a more pragmatic outlook:

Extract 4d.119 – “I do get cross when people say ‘we got consent’, you can’t you know, if someone’s got one-word level of understanding, no you’re not going to get consent.” (Elaine, professional therapist)

Elaine refers to the problem of capacity for people with very limited understanding. Her conclusion appears to suggest that it is impossible to follow a true consent procedure for these service users. This relates to the problem of capacity, as discussed in the following extract:

Extract 4d.120 – “it’s really difficult to get consent for people with learning disabilities, severe learning disabilities, when quite often they haven’t got the *capacity* to consent that’s where it’s really hard...” (Marie, nurse)

Marie relates to personal experience in obtaining consent for behaviour therapy interventions. She mentions the concept of capacity, which describes a person’s ability to comprehend and retain information. This ability will vary for each individual:

Extract 4d.121 – “it comes down to capacity to consent...again with learning disabilities, folks are gonna have different people who have *levels* of understanding.” (Eva, social care professional)

Varying degrees of capacity and understanding identify a complex problem. This situation seems to imply that there is no standardised procedure for gaining consent, as Catherine explains:

Extract 4d.122 – “we just have to be mindful about consent isn’t as the *tradition* we’re..as you sign a piece of paper sort of understanding what you’re signing, its...we have to just be a bit more creative with gaining it. [...] I had one client who I’d taken an object of reference with me and I did it and she used to take it straight to the front door to say ‘go away’ so we were taking that as a sign, she didn’t want me that day and that was her way of saying ‘go away I don’t want you’.” Catherine (occupational therapist)

Catherine outlines her approach for consent. I believe that this extract reveals a difference between permission and consent. Catherine may gain permission from the service user, but she has not gained informed consent. A method such as this may be effective in a standard treatment scenario, but research decisions are likely to be more complex, and require more capacity for abstract thought. There appears to be a balance between autonomy and proxy decision making:

Extract 4d.123 – “Well obviously you try to get consent from them wherever possible, you know the theories of autonomy are very important and if someone’s able and can...capable of making decisions for themselves you should try your very best to explain it in the best possible way what you’re trying to do, and so they understand it. Obviously if they *weren’t* able to understand it you’d go to the person that’s mainly responsible for them and gain consent from *them*.” (Carla, nurse)

Carla advocates the principles of autonomy but she also acknowledges the limitations in this context. She sees no problem in approaching the legal guardian if the person in question cannot understand the research procedure. Making a proxy decision for someone who lacks capacity to provide informed consent is a difficult issue. Many interviewees referred to their decision to



provide permission for a service user to take part, which they felt was in the best interests of the service user:

Extract 4d.124 – “Best interests should be applied. What’s in their best interests.” (Mark, nurse)

A problem with the idea of best interest is outlined in the following extracts:

Extract 4d.125 – “And then it’s looking at best interests...and *that* can be...manoeuvred to someone’s...else’s best interest, i.e. families or carers or things so, that’s where it is difficult.” (Marie, nurse)

Extract 4d.126 – “some folks with learning disabilities are not able to communicate and others need to speak for them, its determining whether those people *have* their best interests at heart.” (Eva, social care professional)

Marie and Eva highlight potential conflicts of interest between the best interest of service users and of other parties. Eva implies that this conflict may not be immediately obvious, and may need to be determined. This is a warning that carers and families should not always be assumed to have a service user’s best interests at heart. These complexities surrounding proxy decision making have given rise to various approaches that stakeholders can employ in order to gain informed consent from people who lack the capacity to provide it for themselves. As with paid carers, the process of consensus decision making was preferable for many interviewees, beyond a certain point:

Extract 4d.127 – “I think it’s important to gain consent as *much* as possible from the client and the individual and we often will offer a service to a client and if they’re actively showing the signs that they don’t want us and they don’t want our input then we take *action* as consent as well as going to family and professionals and other people involved, depending on obviously their level of ability.” (Catherine, professional therapist)

Importantly, the approach described here includes the service user in the consensus. Her description seems to include carer and family views, but she places emphasis on the service user's actions. This shows a practical attitude to gaining consent without reference to a formal framework. However, some interviewees mentioned the need for an official framework to seek consent:

Extract 4d.128 – “we need to have a *multi-disciplinary* team meeting for the benefit, to see whether it is for the *benefit* or for the goodness of the client. Is benefit the client yeah. In other words you can get the consent from the multi-disciplinary team on behalf of the clients.” (John, nurse)

John refers to a multi-disciplinary consensus in order to gain consent. His words echo a feeling of teamwork in order to achieve benefits for the service user, as paid carers have also described. Marie describes how this multi-disciplinary framework for consent could take place:

Extract 4d.129 – “you could have social worker, community nurse, speech and language therapist, OT...consultant psychiatrist *a/ways*, clients' carers, family, client *usually* depending if they want to come in but usually they're there, could be someone from the Behaviour Therapy Team, so there's a *lot* of people” (Marie, nurse)

Marie describes the variety of stakeholders involved in multi-disciplinary consent process. A meeting involving many different professionals requires time and organisation, possibly delaying the consent process. However, multi-disciplinary meetings were popular due to the perceived complexity of the consent process for those without the capacity to provide it:

Extract 4d.130 – “It's obviously a *complex* matter, however I feel that a multi-disciplinary *type* of community or team to offer consent in those cases, appropriate in people from professions, their family and as well as advocacy service.” (Sayeed, clinician)

Sayeed mentions including advocacy services into the multi-disciplinary approach. The Mental Capacity Act has since made independent advocates

mandatory for people with no legal guardian. However, at present this only relates to consent for severe medical treatment. The need to involve multiple people, particularly carers with close relationships with the service user, arises again below:

Extract 4d.131 – “it *must* involve people who know the person well. If they’ve got a communication problem, then we *must* have people who know that person really well...supporting them.” (Alice, professional therapist)

Nevertheless, some warned about the need to ensure that the service user is being heard, placing an emphasis on service user autonomy:

Extract 4d.132 – “people with learning disabilities are people and you should make absolutely no assumptions about their understanding of the need for research or their willingness or otherwise to participate in it.” (Janice, professional service manager)

It is interesting to note that Janice offers no solutions to the problem of gaining informed consent, apart from relating to the service user’s individual choice. Andrea offers similar opinions when talking about participation in clinical trials:

Extract 4d.133 – “they’re *still* research and they *still* need to have that person’s permission to be able to do it.” (Andrea, nurse)

The consensus seeking approach was popular with professionals, and multi-disciplinary meetings appeared to be a robust way of making decisions in the best interest of a service user who did not have capacity to provide consent. However, these consensus approaches should involve carers who have close bonds with the service user, and care should be taken to understand and accept the service users’ decision wherever possible.

#### **4d.10 Summary**

Professionals' working environments tended to offer them a wider view of the intellectual disability community than any of the other stakeholder groups. This allowed them to conceptualise research within a broader context. Often they were positive about research because they were able to link it to the demands of evidence-based practice or the need to monitor their own effectiveness. This provided a link in which research, such as an RCT, could influence how resources were appropriated in the area. Like carers, emphasis was placed on the need to conduct meaningful, practical research. Unlike the other stakeholders, there was far more emphasis on the need to disseminate research findings to others in order to share knowledge.

Nevertheless, professionals reported experiencing difficulties throughout the trial period. Many of them described preferences for allocation to the Behaviour Therapy Team, since in many cases this was a resource to which they could refer when faced with difficult situations. Redirecting the referral process through the RCT was seen as obstructive at best, counterproductive at worst. Still, many were adamant that this was an essential process in order to develop services for people with intellectual disability in the longer term, and in the wider political climate. Further difficulties arose, as they had done with carers, with the difficulties of communicating in research and the problems of gaining informed consent for complex RCT procedures. Like paid carers, consensus seeking approaches appeared to be the most widely respected.

## **5. DISCUSSION**

Chapter 4 discussed the findings in relation to the main participant groups, service users, family carers, paid carers and professionals. All of the aforementioned stakeholders had distinct opinions about the study, although there were convergent themes in many cases. The following chapter provides an in depth discussion of the results drawn from Chapter 4. The chapter will be split into four sections. Section 5.1 will summarise and interpret the findings from the participant groups. Section 5.2 discusses the findings conceptually, relating them to the research questions and describing how themes interrelate. Section 5.3 relates the findings and theoretical assumptions to those described in previous relevant literature. Section 5.4 discusses the strengths and limitations of the study, outlines implications in relation to policy and practice, and draws conclusions from the data.

### **5.1 Results summary**

#### **5.1.1 The intellectual disability context**

The different sub-samples of service users, family carers, paid carers and professionals provided a variety of perspectives on the theme of an 'intellectual disability context'. Service users appeared to be acutely aware of the fact that they felt labelled and disadvantaged in society. This could cause problems in the fact that they were often uncertain of their own abilities. There was some recognition of the fact that they, as service users, had individual problems that could be quite different to those of other service users. This caused frustration with labelling. The identification with the label was particularly difficult for the most able of the service users who participated in this study, who in reality would have very little in common with those with more severe intellectual disability.

Some of the family carers interviewed in this study also discussed the problems of labelling for people with intellectual disability, however this was far less pronounced as an issue than it was for service users. Moreover, there was further recognition that people with intellectual disability were a diverse group

whose needs should be assessed whilst preserving a person's individuality. Family carers' overriding feelings about their situation related to isolation and frustration. They often encountered difficulties in obtaining professional help and support for the service user. This gave rise to strong feelings that there was insufficient funding and resources available to serve this population adequately, and that provision was inconsistent.

Paid carers reiterated the point that people with intellectual disability were a varied group. One theme that was particularly noticeable within this sub-sample was that they appeared to have a problem solving attitude when seeking help and support for service users. Paid carers were often familiar with pathways of seeking help with professional services, seemingly more so than family carers. They often felt that they could understand their clients better than professionals could, since they worked with them on a more regular basis. They also tended to remark upon the limitations in resources for services for people with intellectual disability. Pragmatic problem solving was an integral part of their working lives, and intuitive experience and reactive strategies were often used to alleviate problems. This problem solving approach was often highly respected, although professional help was sought if paid carers had exhausted their options within the team and could not find a solution. This context led many paid carers to instigate participation in the RCT.

Like all the other groups, professionals discussed the individuality of people with intellectual disability. There was accompanying discussion of the disadvantages that this population had. Similar problem solving strategies were adopted to those described with paid carers. Professionals would look within their own team first, there was a pronounced ethic of teamwork, and the aim of this was to achieve a good outcome for the service users. If professionals were unsure about how to proceed with an individual case then they would often seek specialist help. They were aware of problems in communication with service users, and often saw this as a two-way process, with an onus on themselves to use a variety of appropriate communication aids and to facilitate understanding.

### **5.1.2 Opinions about research**

Participant groups were unanimous about seeing research in a positive light. Service users often focused on how research mattered to them as individuals, such as the need to collect personal information. They appeared to be less focused on the wider societal aims of research. Family carers, paid carers and professionals placed particular emphasis on the practical and applied outcomes of research. Research was a good thing if it highlighted gaps in provision for people with intellectual disability. Across all three groups, there was debate about how much the service user could be realistically involved in research, and how much s/he would understand. Paid carers in particular described the difficulties of accurately capturing the more complicated aspects of individuals with intellectual disability. There was also concern across family carers, paid carers and professionals that their views would not objectively represent the views of service users, and there was a certain discomfort in speaking on behalf of a service user who could not represent themselves.

Professionals can be divided into two groups regarding their opinions on research. Some professionals had prior knowledge and experience of research, and some did not. Often this prior knowledge of research was gained through further/higher education; occasionally it was gained through previous experiences as a research participant. Professionals with and without research knowledge described the need for research. Those with knowledge of research often referred to it as a means to support good practice. They made a link between research and service provision, in terms of how the former could affect resources, either positively or negatively. Amongst some professionals there was an interest in research outcomes and how they could be disseminated to others to prevent them from spending resources unnecessarily in carrying out similar research. This showed an appreciation of the generalisability of research findings in a broader context than the local area.

Professionals and paid carers showed regard for the problem of gaining informed consent for research. A consensus-seeking approach involving others from various disciplines and backgrounds appeared to be the most commonly cited process. Family carers relied more on their own judgment to provide consent for a child who did not have capacity.

### **5.1.3 The RCT**

Few of the service users understood all but the most basic elements of the trial. When prompted by the vignette, some appeared to be of the opinion that comparison groups would be useful for the evaluation. However, it was unclear to what extent service users understood that the aim of the trial was to evaluate a service, not to investigate them as individuals. In some instances the role of the researcher was also unclear to the service users. Within this context there emerges a viewpoint that randomisation to two separate groups was not fair on those participants that were allocated to the control group, since they would not receive timely help and support.

Understanding of the trial appeared to somewhat affect how family carers felt about the process. It was clear that some of the family carers who were interviewed had very little knowledge about the aims and procedures of the trial, whereas others understood that they had a chance of being allocated to a control group instead of an intervention group. Some family carers saw the need for this control group, in order to compare the effectiveness of two interventions. Particular difficulties arose in cases where family carers had misunderstood the rationale behind the trial, and when the person under their care was allocated to the control group instead of the preferred intervention group. This caused frustration and confusion on behalf of the family carer, which often arose in the interviews. There was a tendency for family carers to relate randomisation procedures to the belief that those who commission services were trying to save resources, rather than to prioritise who needed the service most urgently.

On the other hand, paid carers often appeared to view the RCT as a way of monitoring the quality and applicability of the intervention being delivered. Some paid carers were unaware of the aims of the trial, and in a similar way to family carers, those that were not aware of the aims tended to have a negative view of the trial procedure. Partial knowledge of the trial was common in this group of stakeholders. Several paid carers made reference to placebo procedures, or the need for comparison groups, which indicated that they understood some of the RCT procedures. Paid carers appeared to be motivated by the fact that they stood a chance of acquiring further help and support for the service user, and



were aware of the fact that enlisting in the trial would likely bring them more support than not enlisting. Altruistic motives on the other hand were less frequently observed in this group.

Taken as a whole, the sample of professionals appeared to have the best knowledge of the RCT aims, and many understood the procedures. They tended to have a better understanding of the remit of the trial; to test the service rather than to investigate particular individuals. This is probably because they had a service-level understanding of the intellectual disability community, and would visit many service users from their caseloads.

Professionals often viewed randomisation as a way of making the study less biased, which again indicates some understanding of the underpinning principles. Amongst professionals with poorer knowledge of research, this was occasionally misconstrued as making the study fairer, such as allowing all service users the same equal opportunity to access the intervention. Those from clinician backgrounds tended to be most supportive of the theory behind the RCT than those from social care backgrounds. However, most professionals showed some preference for service users to be allocated to the intervention group rather than to the control group.

Professionals' concerns tended to revolve around the fact that the trial restricted service provision and made it more difficult for them to refer to other intervention teams in times of crisis. This caused problems within a culture of reactive problem solving, as was seen in both professionals' and paid carers' interviews. This represents a practical concern about the trial, rather than a hypothetical concern about the acceptability of randomisation. However, it is also true that some professionals had strong views against randomisation and trials because of either the issue of whether 'informed' consent was possible or because of a belief that people with intellectual disability would be better suited to a less clinical type of research. Professionals, more than any other interviewees, tended to see the need for appropriate safeguards as fundamental in order to conduct the RCT ethically.

## 5.2 Interpretation

Study findings have thus far been presented in narrative form. Large volumes of data were described within the context of analytic themes from the various groups of participants. These themes were themselves derived from the data, and ordered sequentially. The creation of an ordered narrative artificially imposes linear structure upon the analysis process. In order to explain the data further, it is necessary to present the findings conceptually. This section of the chapter addresses this problem. It will show how stakeholders make decisions within the context of an RCT in intellectual disability. This section will not seek to make irrefutable claims, and the cross-referenced extracts merely provide examples to support the data interpretation.

A service user's capacity to provide consent is dependent upon their intelligence (or level of ability), and the environment. Firstly, people with intellectual disability are often classified clinically according to their level of disability, from mild to profound. Secondly, the environment may influence a person's capacity, such as encouraging feelings of acquiescence amongst service users (Extract 4d.111). Likewise, a supportive, encouraging environment may encourage the service user to make decisions for themselves (Extract 4d.122). The implication for informed consent in research is that capacity is dependent upon fixed and variable factors, which makes it difficult to determine appropriately. This includes the nature of the decision itself, since some decisions are easier for people to make than others.

This interpretation is based upon the assumption that the process of providing informed consent should be conscious and explicit. This may not always be the case (Extract 4d.117). Participants may therefore provide consent to take part in studies without fully understanding the consequences (Extract 4b.41). Likewise, the concept of 'capacity' itself represents a key assumption. It is to some extent socially constructed, so it will always be difficult to gauge. One service user may have good speech comprehension and be poor on functional tasks; another service user may have opposite strengths and weaknesses. Service user involvement in the RCT may provide an indication of capacity.

However, this level of involvement is dependent upon others' views about service users' abilities (Extract 4b.36; Extracts 4d.79 – 4d.80).

To some extent these difficulties found in the population of people with intellectual disability are also true within the general population. However, for service users with a variety of disability, these differences are magnified. In effect, this summarises the core of the thesis argument.

Variations and deficiencies in service user capacity imply the involvement of other stakeholders. This can be thought of as a 'decision group'. For people with mild or borderline intellectual disability, this group may include the service user only. However, family members or professional carers are likely to be involved. The number of carers may vary; a service user living in a staffed residential home may have meaningful relationships with several carers. Furthermore, residential carers are likely to interact with managerial staff. In these cases, the residential home manager influences the consent decision. In many cases the service user may live in the family home, family members therefore become important stakeholders.

The participants of the REBILD trial were referred to health professionals for displaying challenging behaviour. Two potential problem solving strategies have been identified by the stakeholders in this study; coping using the resources internally available (Extracts 4c.14 – 4c.15) and actively seeking help from external sources (Extract 4a.12). The two strategies are on opposite ends of a continuum. Coping without external help represents one extreme. For most manageable problems, carers or service users may speak to peers, managers, relatives or friends (Extract 4c.16). The process of seeking help from professionals may occur for particularly difficult, urgent or long-lasting situations (Extract 4c.10). Decisions to seek external help are dependent upon expectations and prior experiences. For example, coping using the resources internally available may seem appropriate if the carer or service user has negative prior experiences with health and social care professionals. Successful strategies are likely to be reinforced over time in response to familiar problem situations.

Active help seeking strategies expand the stakeholder decision group to include professionals. Community nurses and social workers were often asked to provide input on consent decisions. Sometimes multi-disciplinary meetings occur. These include people from various positions within the service along with service users and primary carers. Professionals who join the decision group may go through similar processes to carers and service users, as outlined above. Professionals may consider the problems and needs of a situation. They may adopt help seeking strategies based upon prior experiences, providing input, consulting with peers or seeking external support (Extract 4d.36).

The perception of funding and the availability of resources are key factors. Stakeholders from all backgrounds perceived the lack of resources as a problem. This may influence the strategies for seeking help, as described above (Extract 4c.15). Stakeholders will be more likely to employ self-sufficient, ad-hoc help strategies if there are inadequate professional resources to deal with the problem (Extract 4a.11). Stakeholders from all the participant groups may resort to coping internally because they perceive that available resources may disappear in future. In any case, stakeholders held perceptions that resources were insufficient.

Nevertheless, stakeholders can influence resource provision. Family carers and service users can pressurise professionals and acquire access to help (Extract 4b.21 – 4b.22). Senior managers in intellectual disability services are unlikely to be involved in the decision group for an RCT, but they can influence the wider context by making decisions about service provision (Extract 4d.41). These decisions by service managers are dependent upon funding bodies. The majority of funding for intellectual disability services in the United Kingdom comes from Government-funded agencies such as Social Services and the NHS. The NHS Trust involved in this study had achieved some financial autonomy as a Foundation Trust, which complicates the link between the Government and the provision of resources.

The decision group may vary and evolve. Stakeholders assume various roles within the group. These roles assume relative importance dependent upon the

situation. For example, a service user with mild intellectual disability and minimal contact with their family may require the assistance of paid care staff for several hours per week. A service user with more severe intellectual disability and reduced capacity may require the ongoing presence of a carer. Any problems experienced by the service user or carers can involve other stakeholders, such as peers or senior staff. If available, they may consult health and social care professionals. Professionals may discuss the case and make referrals to other relevant professionals. The decision group may encompass a multi-disciplinary team including numerous individuals. Ultimately, the decision group is no more than the existence of a decision itself, which arises from the recommendations of group members.

The existence of a 'decision group' is the primary assumption of this interpretation. It is based upon the network of relationships between potential stakeholders. Service users, paid carers and professionals all reiterated the importance of relationships in decision making (Extract 4a.30; Extract 4c.42; Extract 4d.130). The number and variety of the stakeholders in the group will vary according to the views of the paid carers, family members and service users in the immediate circle. The relative weighting of the opinions within the decision group will vary from case to case. Each group member's opinion may not necessarily be equal (Extract 4b.34; Extract 4d.129), such as when the service user is judged to lack capacity.

The importance of the decision group becomes apparent in Figure 11, describing the precedent for a decision to participate in research and clinical trials. Each stakeholder within the group is likely to influence the others. This in turn influences the success of the RCT in practice.

**Figure 11** – Perception of participation in clinical trials

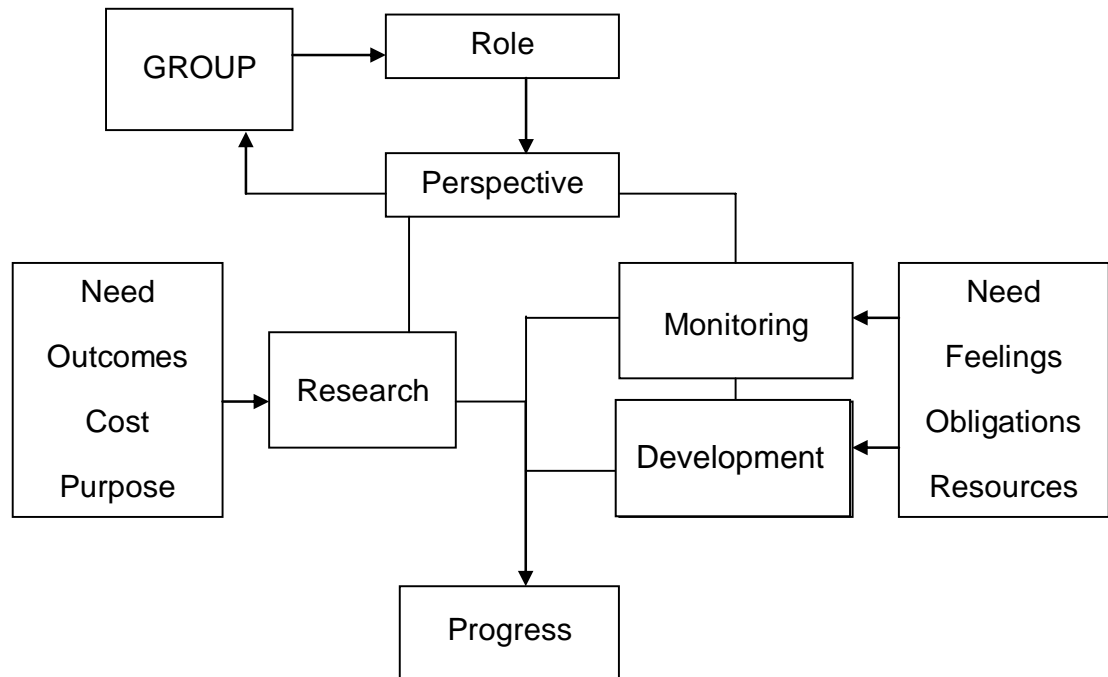


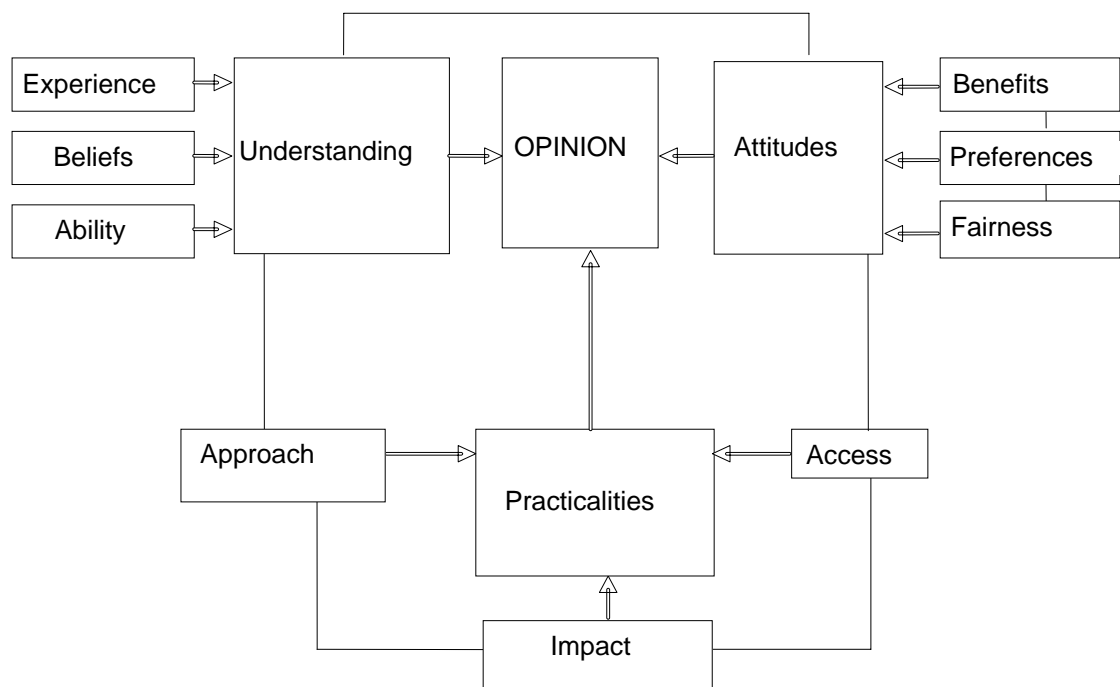
Figure 11 illustrates how perspectives of research, service monitoring and service evaluation may relate. Perceptions of these concepts may be influenced by an individual stakeholder's role within the decision group. For example, the perception of a consultant psychiatrist with years of experience of clinical research is likely to differ to that of a family carer. With this in mind, perceptions of clinical research appear to be dependent upon four factors; the need for research, perceived outcomes, potential cost, and the reason why the research was conducted. Need is based upon the perception that research will help people and make improvements (Extract 4b.26). This links with expectations of research outcomes. Outcomes should be practical, applicable and appropriately disseminated (Extract 4d.21 – 4d.22). Benefits gained from research outcomes are balanced against any potential cost of conducting the research, such as the distribution of resources (Extract 4d.32). Stakeholders are also influenced by their feelings about why the research is being carried out (Extract 4c.58).

Stakeholders discussed the importance of maintaining the quality of intellectual disability services, through processes such as monitoring and development. Service monitoring referred to audit, and to regulatory bodies such as the Commission for Social Care Inspection (CSCI), which are employed to check

the quality of residential care homes. Carers and professional participants were familiar with these processes, as they help maintain quality standards (Extract 4b.24; Extract 4c.33; Extract 4d.53).

Development referred to the process of evidence-based practice (Extracts 4d.55 – 4d.58). There was a perceived need for evaluation within the framework of the NHS, and in order to provide theoretical knowledge about improving services. The processes of monitoring and development were often seen as an obligation to service users. They would help ensure that resources were being well spent, and provide evidence for future resource provision. The desire to make progress underpins positive attitudes towards research (Extracts 4c.22 – 4c.23), and it creates tolerance for processes such as monitoring and development. Stakeholders' perceptions of RCTs operate within this context, as Figure 12 presents:

**Figure 12** – Factors influencing stakeholder perceptions of RCTs



Opinion is affected directly through understanding and attitudes. These two latter concepts mutually influence each other (e.g., Extracts 4c.53 – 4c.54). They also influence perceptions about the practicalities of conducting RCTs in this context (Extract 4d.76). Therefore, an opinion of the RCT 'approach' develops, and of the RCT's applicability.

Understanding of an RCT is influenced by several factors. As described earlier, previous experience and clinical research training improves understanding of scientific concepts, and experience with similar methodologies improves understanding further (Extract 4d.63). Beliefs are also important in developing understanding, and of particular importance are beliefs about the research team's rationale for conducting the RCT. Participants may continue to believe that treatment or intervention will be allocated according to their individual needs, rather than being randomised (Extract 4b.41). Thirdly, the perceived level of service users' ability was seen to be important in determining their understanding of concepts associated with RCTs (Extracts 4d.79 – 4d.80).

Attitudes were related to beliefs about the benefits of participating in the RCT, both to participants themselves (Extracts 4c.59 – 4c.60), and with regard to longer term benefits from service development (Extracts 4d.28 – 4d.29). Attitudes were also influenced by perceptions of fairness, such as the ethics behind randomising individuals to receive intervention or control treatment (Extracts 4d.83 – 4d.84). More fundamentally, this reflected the inherent preferences about the superiority of the intervention to the control treatment (Extract 4b.40). This essentially fuelled concerns relating to the accessibility of the intervention during the RCT period, which were magnified in situations where the participant was judged to require intervention urgently.

Attitude and level of understanding affect perceptions of the practicalities of conducting an RCT within intellectual disability services. Service users' ability and capacity may limit their potential involvement in RCTs, and the suitability of using the RCT approach was debated (Extracts 4d.75 – 4d.76). The applicability of RCTs was discussed in relation to how the findings would be disseminated. Some professionals advocated the use of inclusive, participatory research models, which emphasise service user involvement (Extract 4d.81), which may also compliment more traditional clinical research.

Another major practical consideration related to ability to access interventions. This predominantly related to their preferences for the intervention over the control treatment. In this context, participants may benefit by accessing treatments or interventions otherwise unavailable in a resource poor



environment. Stakeholders may perceive positive or negative consequences based upon the outcomes of the RCT. This is dependent upon whether the results provide evidence for the effectiveness of treatments or interventions. Such information may be used to influence future funding cuts, which seems to represent a particular fear within intellectual disability services (Extract 4c.58). Opposing outcomes illustrate potential conflicts of interest. The interests of service user, carer, researcher, family, health care professional, social care professional, and funding body may differ (Extract 4d.31 & Extract 4d.34).

### **5.3 Results in relation to previous findings**

The findings relate directly to two broad areas of the published literature. The first describes the idiosyncrasies of conducting RCTs with people with intellectual disability in comparison to other settings. The second area describes the public's understanding and involvement with research and clinical trials. Much of the literature surrounding the latter relates to the concept of the therapeutic misconception (Appelbaum et al, 1987).

#### **5.3.1 RCT settings**

The findings of the present study have illustrated the importance of context in RCTs. Other studies that have sought participant experiences of RCTs have shown this. Moffatt et al (2006) examined participant experiences of a social intervention for a welfare rights service. Their findings describe a relaxed attitude towards randomisation amongst participants. This can be explained by the non-urgent nature of the intervention itself. By contrast, Snowden et al (1997) examined parents' experiences of an RCT that tested a treatment for critically ill babies. Unsurprisingly, they reported some hostile reactions to randomisation. The latter scenario was potentially more upsetting for participants, and the need for treatment was perceived as urgent. This shows how the setting of an RCT can affect upon people's attitudes towards it. Oakley et al (2003) discuss the problems of conducting RCTs within social care settings. They describe the importance of piloting, preparation, and discussion with stakeholder groups, which echoes some of the findings of the present study. They also note that Research Ethics Committees in healthcare may not

be well versed in the practicalities of conducting community based RCTs with social groups, essentially complicating the use of these designs in such settings. Furimsky et al (2008) discuss the difficulties of conducting RCTs in mental health settings. They highlight problems with recruiting and retaining participants who have been admitted for a first episode of mental illness, especially if the patient has yet to accept their diagnosis of mental illness. They also highlighted the need to involve family members into the consent process to gain participation in research.

The findings of the present study show that the context of an RCT with people who have intellectual disability is likely to traverse boundaries between clinical and social care. This complicates matters for those who wish to conduct RCTs. Systematic reviews of non-pharmacological interventions repeatedly demonstrated the lack of pragmatic RCTs in the field of intellectual disability, for example; for epileptic interventions (Beavis et al, 2007), for interventions for aggression (Hassiotis & Hall, 2008), and for interventions for sex offenders (Ashman & Duggan, 2008).

The field of intellectual disability straddles both fields of social care and mental health. The RCTs that have been conducted with this client group faced several common problems. These problems include relatively small sample sizes (e.g., Braam et al, 2008; Tyrer et al, 2008; Dowling et al, 2006; Martin et al, 2005; Llewellyn et al, 2003; Willner et al, 2002) and high drop-out rates among participants (Kerr et al, 2005). Although sufficiently powered, the REBILD trial itself had a small sample (63 participants), although the dropout rate was low (3 participants).

Kerr et al (2005) note the difficulties of conducting RCTs within a heterogeneous population. Potential variations in participants' type and range of disability are difficult to control for, and the authors recommended extended recruitment periods to balance against this problem. In the present study, professionals, carers and service users all mentioned heterogeneity as a barrier to conducting clinical research, they made repeated references to the difficulties of drawing conclusions from a population with such a wide range of ability and disability. People with intellectual disability were nonetheless seen as a varied

group who differed greatly in their capacity and level of ability. In practice however, randomisation may be able to account for a certain degree of participant heterogeneity through sample stratification.

The findings of our study described the concept of a 'decision group'. This was defined as collection of stakeholders who may support the service user in their decisions, throughout the RCT. The carer or family member often acts as a primary point of contact. Participation follows permission gained from parties considered relevant, such as the service user and other possible stakeholders. Similar decision groups are likely to exist in other clinical populations with diminished capacity, such as people with Alzheimer's disease (Karlawish et al, 1999) or schizophrenia (Jeste et al, 2003). In the general population, this may merely involve a shared decision between patient and doctor (Mancini et al, 2007). Decision groups represent a dynamic process.

Further problems were identified with regard to service structure. Oliver et al (2002) show the problems of gaining co-operation from local intellectual disability services. The organisation of intellectual disability services is often idiosyncratic, and they identified significant variation in service structure between different professional teams. Lennox et al (2005) identified 17 tiers of management within one intellectual disability service. To a lesser extent, this was paralleled in the current study. REBILD was conducted within one NHS Trust, but significant differences were seen in the organisation between the five sectors. Furthermore, as for other populations such as older adults, there are complex boundaries between health, social care, and private residential care companies. This underlines the importance of gauging the various stakeholder opinions and experiences throughout the study period.

Martin et al (2005) discuss the importance of forming relationships with 'insiders' in order to aid recruitment. Third-party stakeholders were seen to 'gate-keep' and block access to potential participants (Lennox et al 2005; Oliver et al 2002). The present study underlines the significance of gate-keeping. Rather than seeing third party gate-keepers as barriers, they may be seen as potential facilitators within the decision group. This facilitation is particularly relevant where communication difficulties are present. Martin et al (2005) report

the difficulties of identifying important third-parties, and Charuvastra & Marder (2008) note the importance of gaining trust for researchers and clinicians during RCTs. The present study demonstrates the need to establish trust and to work in partnership with those closest to the service users, such as keyworkers, and also with those more equipped to make decisions, such as residential care managers or multidisciplinary professionals. It is unlikely that third-party stakeholders will help facilitate participation into an RCT unless their trust has been gained.

Oliver et al (2002) suggested that local stakeholders may be hostile to the principles of evidence-based practice. In the present study, professional interviewees often made links between evidence-based practice, funding bodies, and resource provision. Some interviewees expressed negative views towards evidence-based practice, but the majority did not. The majority expressed a preference for the intervention group over the control group, but these preferences did not often explicitly relate to assumptions about how effective the intervention would be. Indeed, several interviewees mentioned the dangers of governing service development by opinion, and that interventions should be assessed to ensure best practice and cost-effectiveness. This does not appear to contradict the principles of evidence-based practice.

More likely, participants' preferences to be allocated to the intervention group over the control group reflected the culture of problem-solving within a resource poor community. Toroyan et al (2003; 2000) suggest that resource poor contexts present opportunities to conduct pragmatic RCTs. They conducted a trial to test a day care intervention for pre-school children in the UK. The lack of resources led to limited availability, so random allocation was used to determine access to the intervention. The only aspect that distinguished participants from non-participants in this case was the fact that participants gave consent for data collection, since both participants and non-participants were randomised to receive the intervention.

The process of limiting resources within the context of an RCT has a long history. During the first true RCT (Medical Research Council, 1948), Streptomycin was in short supply and was made available only as part of a

randomised trial. Kukla (2007) argues that the principles of equipoise are difficult to apply where resources are scarce. Edwards & Kirchin (2002) debate the practice of conducting RCTs in resource-poor contexts; they suggest the procedures used by Toroyan et al (2000) may not be applicable if the interventions have already been made publicly available. They recommend that any decision to ration resources through random allocation should be made independently of any decision to conduct an opportune RCT. This scenario reflects the situation described in the present study, where specialist behaviour therapy intervention had been available in the local area for several years prior to the RCT, and access had been limited through a waiting list system of prioritisation.

### **5.3.2 Participant understanding**

Canvin & Jacoby (2006) argue that in order to understand an RCT, the participant must first be able to understand their own diagnosis. As shown in Chapter 4, intellectual disability is a particularly complex diagnosis encompassing a range of biological and social factors. These factors include institutionalisation, labelling, and the nature of relationships with others. Furthermore, intellectual disability is likely to directly impact upon an individual's capacity to understand. For this reason, the context of intellectual disability presents its own connotations, which should be borne in mind when discussing how stakeholders understand RCTs.

A practical problem with RCTs is that participants find them particularly difficult to understand (Moffatt et al, 2006), or may have an aversion to the procedure and refuse to participate (Fallowfield et al; 1998; Llewellyn-Thomas et al, 1991). There is a body of scientific literature that has sought to explain how participants conceptualise RCTs, and much of this has focused upon the problem of the therapeutic misconception (Appelbaum et al, 1987). This concept has enjoyed widespread use since its inception, as noted by Appelbaum & Lidz (2006).

Henderson et al (2007) suggest the participants need to understand the following five domains in order to avoid the therapeutic misconception:

- Scientific purpose

- Study procedures
- Uncertainty
- Recognition of the clinician as an investigator
- Adherence to a study protocol

Purpose relates to perceptions of the research team's rationale for conducting the study. Procedure relates to the use of control groups and random assignment during the course of an RCT. To some extent, these first two domains have been discussed within this chapter; the majority of service users (along with some carers) misunderstood the scientific 'purpose', or rationale, behind the trial. They instead believed that the purpose was to find out about their own experiences, rather than to create generalisable knowledge. Similarly, they often misunderstood the study procedure, believing that the intervention would be allocated according to their individual needs as participants.

The other three domains related to the study findings less directly. The domain of 'uncertainty' describes the need for stakeholders to understand that clinicians and researchers may be uncertain about the benefits of competing interventions and treatments. To some extent, this uncertainty was represented through interviewees' beliefs about the need to monitor and evaluate services. Many stakeholders described the need for intellectual disability services to be accountable both to service users and to commissioners. This process was perceived to maximise the efficiency and effectiveness of services. Nevertheless, it is debateable whether this represents an understanding of uncertainty as Henderson et al (2007) intended. Only a minority of stakeholders showed a position of equipoise with regard to the behaviour therapy intervention, and most displayed preferences for allocation to the intervention group over the control group.

The need to recognise the clinician as a research investigator was to some extent diminished within the design of this pragmatic RCT. In this case, the independent research team were aided by local clinicians. The clinicians referred patients to the behaviour therapy intervention, in just the same way as they would have done outside the context of the trial. It was the independent researcher, instead of the clinician, who then contacted, recruited and assessed

the participants for the purpose of the RCT. Even within this framework, a minority of carers (and some service users) appeared to be confused about the role of the researcher. They believed that their research assessments would affect their own allocation to intervention or control group.

Of the five aforementioned domains, 'adherence to a study protocol' presented stakeholders with the greatest difficulty. Prior to the RCT, the intervention prioritised referrals based upon the perceived urgency of each individual case. This was no longer possible during the RCT, since 50% of the participants were randomised to receive intervention. This was not easy for stakeholders to accept. Understanding the methodological rationale behind strict protocol adherence did not increase acceptance. This corresponds to the findings of Bertoli et al (2007), who found that satisfaction and knowledge about an RCT were not correlated; their sample included 105 patients with arthritis who were participating in an RCT. In the present study, randomisation appeared to be unpopular because it was less flexible than standard procedures. Stakeholders working in the intellectual disability environment were accustomed to an adaptable, problem solving, trial and error approach, which was reflected in how they sought help from services such as the Behaviour Therapy Team.

The prevalence of the therapeutic misconception amongst stakeholders cannot be underestimated. Therapeutic misconceptions seem almost universal amongst people with moderate intellectual disability (Fisher et al, 2006). In cases where the service user has moderate intellectual disability it is arguably more important to concentrate on the therapeutic misconceptions of carers and of other relevant stakeholders. Those who have formed the closest relationships to the service user are better placed to communicate research concepts, costs and benefits, but only if they possess sufficient understanding themselves.

The present study suggests that some carers had difficulty understanding the RCT. Vitiello et al (2005) reported therapeutic misconceptions in 27% of parents of children with autism who had participated in an RCT. Surprisingly, Fisher et al (2006) reported that after reading a case vignette, 70% of participants with mild intellectual disability were able to correctly answer all of

the interviewer's multiple-choice questions regarding randomisation. However, only 32% scored full marks for understanding assessment procedures. This indicates that the participants may understand the hypothetical concept, but be unable to relate it to context. It should be noted that these participants were responding to a hypothetical vignette of an RCT for pharmacological treatment for aggressive disorders. Our study findings support these assertions within a real-world RCT. An understanding of random assignment procedures is insufficient to avoid therapeutic misconceptions.

The reason for this disparity could be due to the fact that traditional models of the therapeutic misconception assume the importance of conscious, logical decision-making. Dixon-Woods et al (2007) argue that this conceptualises understanding in terms of a 'deficit' approach, that is, a technical problem to be alleviated through improved explanation. There is evidence to illuminate the flaws of this assumption. Robinson et al (2004) suggest that 'lay interpretations' of RCTs are unlikely to be informed by scientific understanding. Instead, they are interpretations based upon stakeholders' practical and contextual assumptions.

One example of this can be found in the present study. Several interviewees referred to people with intellectual disability as a social population, not as a clinical population. This refers to the Social Model of Disability (Oliver, 1983), which attempts to locate the problem of disability within society. By contrast, RCTs are likely to be informed by medical models of disability, which ascertain that the disability belongs to an individual. Therefore, it would be a mistake to view lay interpretations as universally false. They are merely interpretations that relate to stakeholders' worldviews. They may not consciously integrate theory underpinning scientific methodology because this theory is based upon a model that they do not follow.

Wynne (2006) criticises deficit approaches, claiming that there is a tendency for scientists and scientific institutions to dismiss lay conceptions as misunderstandings. He relates this to high-profile examples where public mistrust in science has been high, such as evaluating the risks of nuclear power. Accordingly, scientific institutions are deemed to view public 'lay' understanding



in a number of ways; mistrust in science as being due to ignorance, the public being afraid of uncertainty, the public having concerns about risk, the public being incapable of bringing their own valid meanings to an issue, and the public failing to understand facts and benefits. He counters this argument by suggesting that:

*“the evidence about typical public expectations of science is just the opposite of this supposed deficit of process understanding; that is, the public usually takes for granted that things are not as predictable as scientific knowledge claims them to be and is skeptical [sic] about scientific claims to certainty.”*

Stakeholders in the present study showed evidence of supporting this assertion. One of the most prominent examples was related to the perceived difficulties of quantifying outcomes. Several participants displayed scepticism about the applicability of quantitative approaches to measure changes in challenging behaviour over time. Some saw this as a reductionism, which would fail to describe their situation accurately. People with intellectual disability were seen as a highly variable social population, where it would be difficult to measure outcomes with great accuracy.

Regardless of whether lay interpretations of RCTs are valid, they have the potential to misinform participants about the consequences of participating. Heaven et al (2005) suggest that participants who assume lay interpretations may see randomisation as a breach of trust between the clinician, researcher and participant. Anxieties about randomisation occur in the light of practical problems, such as the perceived need to urgently access an intervention. Lay interpretations about the potential impact of the RCT may have negative consequences for those researchers and clinicians who wish to build relationships with stakeholders. Essentially, there is a need to inform participants about the potential impact of the research study (Wendler & Grady, 2008), and to increase public awareness of research. These implications will be discussed within the following section.

## **5.4 – Study implications**

The final section of this chapter will discuss the implications of this research. First, the strengths and limitations of the present study are appraised in relation to methodology and scope. Following this, the study will be related to trends in policy and practice. Finally, recommendations for the direction of future research will be outlined.

### **5.4.1 Strengths and limitations of the study**

The study has several methodological strengths. Firstly, the qualitative methodology and analyses were appropriate to explore stakeholder experiences. Previous studies have used quantitative surveys of satisfaction and understanding, which have had limited usefulness. The fact that the interviewees existed within the context of a real-world RCT is significant. Previous studies with hypothetical trial situations are limited in applicability to pragmatic scenarios. Furthermore, the breadth of stakeholders interviewed in this study allows for a greater understanding of the situation. This also delays the point of data saturation, since interviewing stakeholders from different backgrounds contributes a wealth of different opinions and experiences. Triangulation through the collection of contextual data and clinical records provided the study with greater rigour. All in all, the scope of this study extends beyond the boundaries of previous studies of stakeholder experience and understanding of an RCT. This is true for both the intellectual disability field and within the wider literature.

For the most part, the data analysis strategies used in this study were appropriate for the method and the research question. Data analysis was driven by the research aims and served to answer the questions in a relevant, expansive way. The semi-structured interviews were open enough to allow interviewees to explain their experiences and opinions in depth and context. The use of the vignette served to remind interviewees of the trial procedure, and provided information about how the RCT was conducted. This was important because interviewees were interviewed over six months after agreeing to participate in the RCT, and so may have forgotten much about the RCT.

However, using the vignette and interview schedule can also be seen as a limitation. It may have imposed artificial structure upon the interviews. By extension, it could be seen as forcing and directing the data collection through preconceived ideas.

Another important limitation was that only one geographical area was studied, and specific discussions of context cannot be wholly transferred to other areas. However, it is notable that many of the theoretical principles have been shown in previous studies with different study populations. With these principles in mind, this interpretation of the study can be transferable to other contexts. The findings reveal theoretical and methodological principles, broader concerns regarding consent and capacity, concerns about limited resources and concerns about practicalities of applying the medical model within this population of individuals. These concepts form the core of the findings, and are more likely to be transferable to other geographical and situational contexts. These results apply to pragmatic RCTs of psychological interventions, but may apply to Phase III RCTs of pharmacological treatments. The methodological principles, concerns regarding consent and capacity, and context of limited resources are likely to be transferable.

A more relevant criticism regarding applicability is the extent to which the interviewees represented the broader intellectual disability community. It was impossible to capture the views of people with severe intellectual disability and/or no verbal communication, and it was difficult to interview sufficient numbers of service users because many participants of the REBILD trial had severe intellectual disability. The problem is magnified within semi-structured interviews, which may not be ideal for people with more severe intellectual disability, since they seek a degree of depth. It is possible that the use of interactive focus group media such as Talking Mats® may help to circumvent these problems (Murphy, 2006).

The method of recording the interviews represents a methodological choice. In retrospect, audio-recording interviews with people with intellectual disability may not have been the most effective method. Two service user interviewees preferred not to be audio-recorded, although they consented to have written

notes taken during the interview. Interestingly, these two interviews were far more successful than audio-recorded interviews with two other service users. This may reflect a lack of confidence amongst people with intellectual disability when faced with audio-recording apparatus. If conducting similar interviews in the future, a dynamic combination of audio-recording and written notes would be preferable. Moving from one to the other should be based not just on consent but on interviewees' apparent level of confidence, as gauged by the interviewer.

A number of minor criticisms can be made regarding study design. Firstly, all the carer and service user interviewees had participated in the REBILD trial, and none of the participants with intellectual disability (n=6) who declined to take part in the RCT were available to be interviewed. Secondly, the time between participation in REBILD and participation in a qualitative interview differed between interviewees. Ideally, participants should have been interviewed immediately after consenting, and then again after final follow up. However, this was impractical due to time constraints and the importance of collecting RCT data in parallel, as it may have also impacted on the RCT outcomes.

Lastly it is important to mention that many of the interviewees were acquainted with me prior to taking part in a qualitative interview. This is because I had met the family and paid carers on several occasions during the REBILD data collection phase. I had also spoken to carers and service users on the telephone in order to arrange data collection appointments. Furthermore, I was acquainted with many of the professionals who were interviewed in this study. I had visited each of the multidisciplinary community learning disability teams, the Behaviour Therapy Team, and each of the consultant psychiatrists in the local area. These visits were carried out originally in order to introduce the REBILD trial and to describe the processes of randomisation. I had often also visited professionals' offices in order to audit participant records as part of the data collection for REBILD. Therefore, I was likely to be seen within the local area as the most public face associated with the REBILD trial. This approach offers advantages and disadvantages regarding the present study. On one hand, it allowed me greater access to larger numbers of participants who already knew

me from previous work. It also increased the amount of trust that interviewees had in me, which may have encouraged interviewees to have been more candid than they would otherwise have been. On the other hand, it could have prevented people from sharing more negative feelings about the RCT, since I may have been seen as an ‘ambassador’ for REBILD.

Nevertheless, the findings should encourage future researchers conducting RCTs with people who have intellectual disability, by providing information on how to improve participation and collaboration between researchers and stakeholders.

#### **5.4.2 Implications for policy and practice**

The conduct of RCTs is responsive to the stringent requirements of international law. The guidelines for good clinical practice are provided in the following definition from the EU Directive for Clinical Trials (European Parliament and the Council of the European Union, 2001):

*“Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.”*

Within intellectual disability services, a number of recent UK reports have uncovered potentially abusive treatment of people with intellectual disability within services (Commission for Healthcare Audit and Inspection, 2007; 2006). Furthermore, the old South Ockendon Hospital lay within the catchment area for REBILD study, and was a living memory for many stakeholders. The damning South Ockendon Report (Inskip, 1974) instigated the closure of a large institution within the UK by highlighting abuse and malpractice. With this background, concerns about poor standards of service provision possibly carried more relevance than concerns about the ethics of a research study. The implication is that people may be more accepting of the potential benefits of research; especially those that seek to make improvements and reduce bad practice.

The UK white paper 'Valuing People' (Department of Health, 2001) outlined the need to assess the quality and sustainability of health and social care for people with intellectual disability. The more recent 'Valuing People Now' (Department of Health, 2007) reemphasised the importance of such assessment. RCTs are seen as the most reliable way of providing scientific evidence for treatments and interventions. However, this study has highlighted the complexity of stakeholder views surrounding evidence-based medicine and service assessment. Stakeholders were unanimously positive about research, and many of those working within professional services were supportive of the principles of evidence-based practice. Therefore, it would appear that the intellectual disability community is keen for research to develop within this field. Views on research methodology tend to relate instead to ethical and practical problems encountered with pragmatic RCTs, rather than a broader suspicion of research.

Problems of consent, communication and capacity to participate provide barriers to the research process, which can only be overcome through developing relationships with local stakeholders. The Mental Capacity Act (Department for Constitutional Affairs & Department of Health, 2005) has been the most significant recent addition to policy affecting work with people with intellectual disability. This Act legally enshrines codes of practice for mentally incapacitated adults, including research participation. Encouragingly, most interviewees' views were consistent with the Act. The researcher or any other stakeholder should not judge capacity on age, appearance of condition, and should encourage the individual and enable service user autonomy wherever possible. The discussion of labelling emphasises the importance of this, and sometimes people with intellectual disability may lack confidence to make decisions. Furthermore, the present study showed that many paid carers and professionals were sceptical of their own ability to make decisions on behalf of service users, and that they would prefer to seek a consensus decision. Paid carers were also often aware of their own inability to speak on behalf of a service user with any objective accuracy. These findings are encouraging in light of the Act, since both the REBILD trial and the interviews for the present study took place prior to implementation. This suggests that many of the

clauses outlined in the Act were common sense and common practice to stakeholders, with one exception.

The standard of 'best interests' is one of the concepts defined by the Act. This allows stakeholders to make a judgment about the best interests of the incapacitated person, following a specific protocol outlined in the Act:

*"The person making the determination must consider all the relevant circumstances and, in particular, take the following steps.*

*(a) whether it is likely that the person will at some time have capacity in relation to the matter in question, and*

*(b) if it appears likely that he will, when that is likely to be.*

*He must, so far as reasonably practicable, permit and encourage the person to participate, or to improve his ability to participate, as fully as possible in any act done for him and any decision affecting him.*

*He must consider, so far as is reasonably ascertainable—*

*(a) the person's past and present wishes and feelings (and, in particular, any relevant written statement made by him when he had capacity),*

*(b) the beliefs and values that would be likely to influence his decision if he had capacity, and*

*(c) the other factors that he would be likely to consider if he were able to do so."*

Making this judgment is easier in cases where the person may have lost capacity relatively recently (e.g., Alzheimer's syndrome, recent brain damage). In these cases, carers make judgements based upon their knowledge of that person's personality and wishes. This is more problematic for people with severe intellectual disability, who may have never had the capacity to understand research and to make decisions. The findings of this study show that primary carers learn ways of communicating with service users through daily practice (Extract 4c.34). To some extent, carers will be able to make judgments of service user preferences based upon their knowledge of that person's personality, and through body language cues. However, as several interviewees noted, best interest can be manipulated and turned into the

interests of others (Extract 4d.125 – 4d.126). This illustrates the vulnerability of people with intellectual disability, and the dangers of assuming that other people will maintain this standard. In effect, the Mental Capacity Act provides a legal code for stakeholders.

The perception of lacking resources in the field of intellectual disability provides an important contextual caveat for researchers. In one sense, this perception represents a problem, but it may also represent a reason for positive views regarding research. Within a resource poor environment, there may be scope for testing interventions on the grounds of cost effectiveness, in order to improve their efficiency or to replace them with other interventions that have satisfied the demands of evidence-based practice. However, those who conduct such research also need to be aware of the political implications that this may have. Research that reveals a service to be ineffective may initiate resource cuts, which is likely to be unpopular amongst service users, carers and professionals. This is a careful balance of which researchers should be aware.

#### **5.4.3 Public involvement in research**

Organisations based within the UK have sought to encourage engagement with clinical research amongst the intellectual disability community. The National Institute for Health Research (NIHR, 2007) has instigated the Patient and Public Involvement (PPI) initiative. They argue that public involvement increases the relevance, reliability, and practical application of research. Participatory action research is an inclusive approach consistent with this ideology. This differs from 'traditional' research as it attempts to involve participants in planning, conducting and disseminating research (Ward and Simons, 1998). Some see this approach as transitional towards a full emancipatory approach that would give participants complete control over the research process (Gilbert, 2004). This approach fully recognises the need for stakeholder engagement.

The potential of emancipatory and participatory research has been debated. Firstly, it fails to regard practical limitations relating to service user capacity. Individuals with severe impairments may be excluded (Kiernan, 1999), and it seems more relevant for people with mild intellectual disability. Participatory action research may be driven by ideology (Walmsley, 2001), and may not fit



alongside traditional research approaches (Ward and Simons, 1998). The former suggests that participatory approaches are developing in isolation from practitioners of traditional research, with little opportunity to share information between them. It is noteworthy that only a minority of interviewees mentioned participatory action research, and the approach raises questions about the conduct and relevance of intellectual disability research to service users. A sensitive middle ground needs to be sought between the need for evidence-based practice and the need for public engagement within this group of stakeholders.

Nevertheless, interventions to improve public engagement with more traditional models of research have been largely untested or unsuccessful. Mapstone et al (2007) conducted a systematic review of strategies aimed to improve recruitment in research amongst the general population. The review included 15 experimental studies aiming to test strategies for improving participant recruitment to research. Several types of strategy were identified, such as supplying increased information, financial incentives, making changes to study design or to the consent procedure. The wide range of strategies across the different studies made it difficult for the authors to generalise and make comparisons about whether any of these strategies were effective. Thus, there is continued uncertainty about how to develop strategies to help increase participant recruitment in research. This can be added to the more specific problems that affect research with people who have intellectual disability, such as those involving consent and understanding.

Unfortunately, evidence for interventions to help improve understanding of research has been equally inconclusive. Flory & Emanuel (2004) conducted a systematic review of interventions that aimed to improve participants' understanding of informed consent in clinical research. They concluded that multi-media consent interventions were ineffective, but that educational background was a good predictor of understanding. This finding was consistent with the results of the present study, where professionals and carers with previous experience and training tended to demonstrate better understanding. However, the findings of the present study also show that the increased understanding of RCT concepts does not always lead to increased acceptance

among professional stakeholders. Therefore, increasing understanding may not necessarily lead to increased participant recruitment and retention.

The problems of participant recruitment in RCTs have been appraised in systematic reviews by Abraham et al (2006) and Ross et al (1999). The authors identified several reasons, including time constraints and travel costs, dislike of randomisation, preferences to be allocated to the intervention group over the control group, uncertainty about the outcome of intervention, and concerns about information and consent. The present study emphasised stakeholders' preferences for allocation to the intervention group, which may be common (Madsen et al, 2007), but not universal (Eiser et al, 2005). It may represent a preference for a treatment or intervention that is perceived to be new (Chalmers, 1997).

Comprehensive cohort designs, also known as 'patient preference trials' (Brocklehurst, 1997) have the potential to address the problem surrounding preferences. According to a systematic review by King et al (2005), they could be used as an alternative to conventional RCTs in situations where participants have strong preferences for allocation to one experimental arm over another. Prospective RCT participants are first asked whether they have any preferences. Participants with no preference are randomised using standard RCT procedures, whilst those expressing preferences are allocated to their preferred group. All the participants are followed up. This design is hypothetically attractive and has been implemented into practice (for example Ashok et al, 2005). However, there are practical considerations. A patient preference RCT requires a larger sample than a conventional RCT. This is because they must include a large enough sample of randomised participants, and then must also account for non-randomised participants. Furthermore, recruitment problems limit conventional RCTs in the field of intellectual disability, so careful consideration would be required before implementing these designs.

#### **5.4.4 Future directions for research**

Future research is encouraged to expand upon the methodological and theoretical findings of this study. The REBILD trial demonstrates that small-scale, single-site pragmatic RCTs can be successfully completed within

intellectual disability services. Still, findings from this qualitative study reveal the complexities of participation in RCTs within the intellectual disability community. They also provide clues as to why RCTs in this population have previously been difficult to conduct. Researchers and clinicians conducting future RCTs with people with intellectual disability are encouraged to investigate and monitor service user relationships throughout the trial. Engaging with various stakeholders is especially important to gain trust during participant recruitment. This is common sense, but may be difficult to achieve in practice. The concepts developed through this study illuminate stakeholder relationships and may allow researchers to conduct clinical research more effectively.

The chief concept regarding stakeholder relationships is that of the decision group. This idea is likely to be transferable to other areas within this field, but construction of the group may differ slightly according to the habits of local service delivery. Either way, the implication is that clinical researchers should identify stakeholders and seek to understand how they relate to the decision group. A keyworker may be useful as a proxy respondent and as a person through whom the research team can gain trust with the service user. However, he/she may not be able to make the management decisions necessary in order to ensure participation. A senior manager may be able to make such decisions, but may have less influence upon a service user within that service user's daily life. Recognition of stakeholders' roles within this hierarchy is likely to gain trust. The present study indicates that service user networks differ widely, but that the fundamentals of the decision group remain similar.

The present study illustrates the importance of investigating therapeutic misconceptions within live contexts. This allows researchers to investigate stakeholder understanding in relation to experiences and concerns. Interviewees from all stakeholder groups demonstrated a variety of attitudes to randomisation based upon beliefs about fairness, the allocation of resources, practical and ethical circumstances. Much of this understanding was based upon lay interpretation, since most carers, service users and professionals did not appear to relate to the medical model. Instead, people related to the potential perceived impact of the RCT, and to possible outcomes and benefits. Future research within intellectual disability needs to look beyond the medical

model, beyond scientific explanations of randomisation procedures. Instead, these procedures should be described in relation to the impact they may have on stakeholders' lives.

Those who conduct RCTs in the future should be aware of the potential impact that they can have on the local communities of people with intellectual disability. Research is perceived to be important, but researchers and clinicians are likely to perceive the impact of RCTs in a different way to local stakeholders. Impact relates both to immediate concerns regarding the allocation of resources through randomisation, and also to the longer term impact after the RCT has been completed. In any case, the impact of an RCT has important implications for the provision of resources. Stakeholders need to discuss the likely outcomes of the provision of resources both during and after the RCT has finished.

Nevertheless, researchers conducting research with this population should strike the correct balance. For most service users, carers, and professional stakeholders, understanding the impact of an RCT is likely to be more important than understanding the scientific justification behind it. However, an understanding of the latter may allow the stakeholder to gain a better understanding of the former. For this reason, a stepwise approach may be useful. The researcher should first explain their personal rationale for conducting the study. Secondly, the researcher should explain how participation can impact on the potential participant's life, such as how the random allocation procedure could direct their line of access to either an intervention group or control group. Thirdly, the reason for using a control group should be explained; to compare outcomes for groups of participants. Fourthly, an individual's allocation will be decided by chance, not in accordance with their own personal needs, accompanied by an explanation about why this is necessary. Finally, researchers should explain to the best of their knowledge what will happen after the trial has been completed. The importance of impact and outcome to participants and stakeholders cannot be underestimated, and explanations of the rationale behind an RCT could help them understand this. The findings of this study could lead to the development of training that could help field researchers to understand the potential issues behind research and

RCTs in the intellectual disability context. The findings provide a base from which researchers can be made aware of various potential problems.

Future research should place emphasis on how RCTs impact on their environment, rather than on how and why participants form therapeutic misconceptions. An analysis of stakeholder experiences of research in similar contexts would be one way to progress. The field of intellectual disability provides a good starting point for this kind of approach because it involves complicated networks of stakeholders, and because previous researchers have encountered difficulties in attempting to conduct RCTs.

The necessities of informed consent will continue to present difficulties for researchers in this area. However, it is worth remembering that this problem is widespread and well known within the community of individuals who work with people who have intellectual disability. Researchers who seek informed consent are in a similar position to carers and health and social care professionals who wish to gain informed consent for decisions regarding treatment or housing placements. Fully informed consent for RCTs with service users who have moderate or severe intellectual disability is likely to be impractical.

On a practical level, RCT method is complex, abstract and relies upon the stakeholder perceiving a scientific paradigm. Without this, background, interventions to increase participant understanding are unlikely to work. For people who lack the capacity to provide informed consent, a service user's subjective acceptance of the researcher would appear to be important. This should be judged in the presence of a carer, and the carer would need to be able to demonstrate an understanding of the impact that the RCT is likely to have upon the service user participant.

A positive experience of an RCT is likely to increase the likelihood of future research connections in the area. This would possibly facilitate the provision of RCTs for interventions and treatments with people who have intellectual disability. Clinical researchers still have much to learn about conducting RCTs within this population. One important distinction is that many of the carers and

service users in the present study declared that they would not want to take part in a RCT that was testing a medication for challenging behaviour. The stigma of testing medication with this population appears to be stronger than the stigma of testing services and interventions such as in the REBILD trial. However, these participants had not taken part in a medication RCT and their views were based upon a hypothetical situation. It remains to be seen how stakeholders would describe their experiences of a medication-based RCT, and a future study similar to the present study would be necessary to find out.

## **5.5 Conclusion**

People with intellectual disability represent one of the most varied, seldom heard client groups within our society. The relative lack of RCTs is one way in which this has been reflected. The problems of communicating and gaining informed consent will always present barriers to any work in this area. Still, applied research seems to be almost universally seen within a positive light, so there are no reasons to actively avoid conducting research. The most effective way to improve participants' experience with research is to show them how it can be applied. There are various ways in which future researchers could use the findings of the present study, but it is up to researchers to find new and creative ways to apply their findings back into the community from which they arose. A failure to do this will reinforce a failure to communicate. Researchers and participants will fail to engage with each other, the possibilities for research will be hindered, and the quality of the research will suffer. It is the responsibility of the researcher to try to reverse these trends.

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## 7. APPENDIX

### 7.1 REBILD Abstract

Title: A randomized, single-blind, controlled trial of a specialist behavior therapy team for challenging behavior in adults with intellectual disabilities.

Objective: Community based specialist behavior therapy teams may be helpful in managing challenging behavior but evidence of their effectiveness is limited. This study was designed to examine the effectiveness and costs associated with treatment from a specialist behavior therapy team.

Method: This was a parallel group, randomised single blind controlled trial carried out in an Intellectual Disabilities service in England. Participants were 63 male and female service users with mild to severe intellectual disability who presented with challenging behavior. The interventions included applied behavioral analysis in addition to standard treatment (32 participants) and standard treatment (31 participants). The primary outcome measure was total and sub-domain scores of the Aberrant Behaviour Checklist (ABC) 3 and 6 months after randomization. Secondary outcomes were psychiatric comorbidity assessed at 3 and 6 months using the Psychiatric Assessment Schedule for Adults with a Developmental Disability Checklist (PAS-ADD); and total costs recorded at 6 months. Multilevel modelling was used to compare square root transformations of the ABC scores.

Results: Significant differences were found in the transformed total ABC scores (-0.89 CI -1.74, -0.04) and each of transformed lethargy and hyperactivity sub-domain scores (common intervention effect -0.56 CI -0.97, -0.15). Standard care participants fared worse on the PAS-ADD comorbid organic disorder subscale. There was a clear trend for lower overall costs of the intervention.

Conclusion: The specialist behavior therapy team in addition to standard treatment appears to be more effective in improving challenging behavior and may have financial advantages over standard treatment.

## 7.2 Published review, 2009

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LITERATURE REVIEW



# Randomised controlled trials in learning disabilities: a review of participant experiences

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### Abstract

Randomised controlled trials (RCTs) are considered the bedrock of evidence-based practice. However, they raise important issues about participant recruitment and the ethics of group allocation. In this article we report relevant literature on how participants with learning disabilities and other stakeholders experience RCTs. Five quantitative studies have been published, one reporting on the views of people with learning disabilities and the remainder on carers' views. Despite the methodological limitations of the studies, carers appear to have a positive experience of RCT participation, and people with learning disabilities are able to understand certain aspects of research methods. We conclude that stakeholders are not hostile to RCTs, but the therapeutic misconception may affect their experiences. Further research is required to investigate interventions that might help promote RCTs in learning disabilities.

### Key words

learning disabilities; research ethics; clinical trials; participant satisfaction; therapeutic misconception

### Introduction

A randomised controlled trial (RCT) is a widely used scientific research procedure for testing clinical treatments and interventions. Such a trial compares the effectiveness of a new treatment with a comparison or 'control' treatment including placebo. The allocation for each participant is selected randomly, avoiding potential selection bias. Ideally, the participant and the researcher should be unaware of each participant's treatment during the course of the experiment. This type of clinical trial has become influential in the climate of evidence-based practice (Guyatt, 1992), and is used to test a wide range of pharmacological and psychological interventions. They are considered to demonstrate the most reliable form of scientific evidence (Centre for Evidence-based Medicine, 2001).

RCTs present ethical concerns; some participants are inevitably randomised to a comparison group instead of receiving a new treatment. The traditional ethical justification underlying this process is **clinical equipoise**. The state of equipoise reflects collective professional uncertainty over treatment because there is insubstantial evidence to suggest

that one treatment is superior to another. However, this does not account for participants' own preferences for treatment allocation. Published literature suggests that many participants consent to RCTs without understanding the purpose of the research and the chance of being randomised to a control group (Appelbaum *et al*, 1987; Robinson *et al*, 2004). This procedure is complicated when enlisting as participants people with learning disabilities, who may have impaired decisional capacity and are perceived to be vulnerable.

Tyrer (2007) has reported that most interventions for people with learning disabilities were based on evidence from non-experimental descriptive studies, comparative studies, correlation studies and case-control studies (grade 3), or from evidence from expert committee reports, opinion and/or the clinical experience of respected authorities (grade 4). This contrasts with the evidence base for cancer interventions (evidence from meta-analysis of randomised controlled trials – grade 1a), heart surgery (evidence from at least one randomised controlled trial – grade 1b) and homeopathy (evidence from at least one controlled study without randomisation – grade 2a).





Learning disability presents significant issues for researchers conducting RCTs. Procedures of gaining informed consent are complicated by an individual's ability to understand what is required of them. The *Mental Capacity Act* (DCA & DH, 2005) in the UK enshrines in law the informed consent procedure for mentally incapacitated adults. Section 1 of the Act applies the concept of 'best interest' for people who lack decisional capacity. An RCT involving people with learning disability who may lack decisional capacity invariably involves other parties; family members, professional carers and service workers are also likely to be implicated in any research decision.

Researchers (Oliver *et al*, 2002; Lennox *et al*, 2005; Martin *et al*, 2005) describe common problems of conducting RCTs in this field such as accessing participants, particularly through gate-keeping organisations. The importance of negotiating with relevant stakeholders such as formal carers, family members, service managers and health professionals is apparent. They note that clinical research in this area may be unfamiliar terrain for many participants, compounded by issues of communication

and the difficulty of gaining informed consent. Given the importance of clinical trials in producing sufficient evidence for the efficacy of interventions, we have chosen to focus the article on participant perceptions and experience of RCTs in learning disabilities. Admittedly, the research participation issues are similar across all methodologies, but RCTs have a conceptually complex design and tend to cause greater anxiety in terms of resource allocation.

Five American studies (Aman & Wolford, 1995; McAdam *et al*, 2002; Vitiello *et al*, 2005; Fisher *et al*, 2006; Tierney *et al*, 2007) have examined the perceptions of participants in RCTs, and the issues of capacity to consent to such a study (details are shown in **Table 1**, below). Tierney *et al* (2007) and Vitiello *et al* (2005) used the same cohort of participants.

### The studies

A case control study (Fisher *et al*, 2006) explored the capacity of people with learning disabilities to consent to participation in RCTs. The sample ( $N = 150$ ) included three equal groups:

**Table 1: Summary of articles**

Study	Participants	Methodology	Findings
Tierney <i>et al</i> , 2007	96 primary carers of children with autism and disruptive behaviour	Survey study 10-item quantitative satisfaction survey of a randomised, double-blind placebo-controlled parallel-groups design	95% response rate 96% satisfaction
Fisher <i>et al</i> , 2006	50 people with mild LD 50 people with moderate LD 50 people with no LD	Case control study 19-item questionnaire with vignette to test participant understanding of a hypothetical research scenario	Less understanding of assessment, placebo and right to withdraw in people with LD, Less understanding of randomisation in people with moderate LD
Vitiello <i>et al</i> , 2005	95 primary carers of children with autism and disruptive behaviour	Survey study 13-item quantitative survey measuring understanding of a double-blind placebo-controlled parallel-groups design	95% response rate 99% aware of placebo 72% aware of randomisation
McAdam <i>et al</i> , 2002	17 primary carers of people with LD and aberrant behaviour	Survey study 7-item quantitative satisfaction survey of a randomised, double-blind placebo-controlled crossover design	81% response rate 100% satisfaction
Aman & Wolford, 1995	40 primary carers of children with LD or borderline intelligence and attention deficit hyperactivity disorder	Survey study 7-item quantitative satisfaction survey of a randomised, double-blind placebo-controlled crossover design	64% response rate 88% satisfaction





people with mild learning disabilities, people with moderate learning disabilities and college students of average intelligence. Those with mental illness and other disorders that could affect capacity were excluded. The Assessment of Consent Capacity – Randomized Clinical Trials (ACC-RCT) questionnaire was designed specifically for the study and was used in conjunction with questions based on a hypothetical vignette that described an RCT for medication for aggressive behaviour. The vignette was chosen because challenging behaviour and its treatments are common in learning disabilities. The questionnaire consisted of 19 short paragraphs, each followed by a question. Answers to the questions were scored to give a measure of participant understanding. The results indicate that people with mild and moderate learning disabilities are able to make a choice about participation in research, but were less able to explain the choice made. Randomisation to a placebo group, confidentiality and the right to withdraw were the most difficult concepts for these participants to understand.

Satisfaction with participation in clinical trials of drug interventions was explored by Aman & Wolford (1995) and McAdam *et al* (2002). The former study compared methylphenidate and fenfluramine in children with learning disabilities/borderline intelligence and attention deficit hyperactivity disorder. Four weeks after trial participation, a seven-item questionnaire was sent to the children's parents to explore parents' satisfaction with the RCT process. More than 75% of the respondents believed they had gained a practical benefit in the form of assessments, explanation of medication or treatments for their child, and 88% reported that they would be happy to participate if faced with the same choices again.

The latter study (McAdam *et al*, 2002), a double-blind cross-over RCT of risperidone versus placebo, also included a similar trial satisfaction survey with carers of children and adults with learning disabilities. The survey showed that all the formal and informal carers of the participants were satisfied with the trial outcome, finding the study an acceptable and positive experience.

Tierney *et al* (2007) added an examination of carer satisfaction of a multi-site RCT comparing risperidone with placebo in children with autism and severe challenging behaviour. Following participation in the two-month trial, parents of 96 children completed a survey about the acceptability of the research procedures. The authors used a questionnaire comprising eight multiple-choice and two open-ended questions. The results mirror previous studies; there was a 95% response rate and up to 96% of the respondents appeared pleased with the conduct of the trial, regardless of group allocation and treatment outcome.

Vitiello *et al* (2005) approached parents who had participated in the aforementioned RCT of risperidone versus placebo to examine how well they understood concepts related to RCTs. A 13-item multiple-choice questionnaire was administered. This questionnaire was designed to test a participant's knowledge of concepts such as study rationale, participant

understanding, right to withdraw, side effects, placebo control and randomisation. Overall, parents had a good understanding of most research aspects, but more than a quarter were unclear about randomisation, so their participation might have been based on misconceptions.

## Discussion

### Therapeutic misconception

Robinson *et al* (2005) argues that participants develop alternative understandings of trial mechanics and rationale; a dominant 'lay understanding' can exist alongside a 'scientific understanding'. The lay understanding can lead to the 'therapeutic misconception', a term originally coined by Appelbaum *et al* (1987). Henderson *et al* (2007) provides a definition.

*Therapeutic misconception exists when individuals do not understand that the defining purpose of clinical research is to produce generalizable knowledge, regardless of whether the subjects enrolled in the trial may potentially benefit from the intervention under study or from other aspects of the clinical trial.*

Among carers of people with learning disabilities in particular, therapeutic misconception may be compounded by concerns about historically exploitative research practices. Both the Willowbrook State School experiments (1963–1966; Rothman & Rothman, 1984) and the human radiation experiments (1944–1974; Advisory Committee on Human Radiation Experiments, 1996) used people with learning disabilities as participants.

Vitiello and colleagues (2005) pay attention to the therapeutic misconception in their study because only 72% of their participants understood that receipt of treatment was determined by randomisation. Fisher *et al* (2006) also refers to this problem among participants with learning disabilities; only eight per cent of participants with moderate learning disabilities fully understood randomisation and assessment procedures, in comparison with all participants without learning disabilities. The authors recommend frequent discussion with participants with learning disabilities about the trial, reminding them of their rights of non-participation and withdrawal.

### Quality of articles

All five studies use quantitative methodology, which is limited in terms of illuminating participants' experiences. The instruments used by MacAdam *et al* (2002) and Aman & Wolford (1995) were not validated, and several questions had ambiguous wording or could be seen as leading to a particular response (for example, 'Did you find people in the study friendly and responsive?'). The high response and satisfaction rates in the four surveys might have been influenced by the fact that the questionnaires were administered by the trial investigators. Only one study (Fisher *et al*, 2006) sought the opinions of people with learning disabilities themselves. It is arguable whether parents and carers are able





to report service user experiences accurately. This is particularly true when the carer has no daily contact with the service user (Lennox *et al*, 2005). These methodological limitations provide scope for future research in this area.

### Implications

Problems in RCTs in learning disabilities are shared by scientists in other fields. For example, Snowden *et al* (1997) showed that parents of critically ill babies who had enrolled in a clinical trial had little understanding of the methods of the proposed study. Heaven *et al* (2005) reports participant perceptions of a trial for prevention of stroke. They describe a continuum of identities assumed by participants, from 'experienced medical volunteers' to 'real patients'. Nevertheless, the practical problems of including people with learning disabilities in clinical research are evident. Ward and Simons (1999) describe the participatory research paradigm, which differs from traditional research because it attempts to involve participants in planning and conducting research and being involved in dissemination. Walmsley (2001) argues that inclusive approaches are developing in isolation and with little overlap with more traditional approaches to research. This gap could be bridged by applying participatory approaches within clinical research. An example of this was illustrated in the document *Let Me In – I'm a researcher!* (DH, 2006) which describes how people with learning disabilities can be full participants in research projects.

RCTs underpin improvements in the efficacy of pharmacological and psychological interventions but their success is influenced by participant input. This review shows that researchers are beginning to recognise the importance of the consumer/participant experience. There is therefore impetus to ensure that potential stakeholders are informed about the process, and are sufficiently content with taking part. This would increase ethical quality and help minimise the therapeutic misconceptions experienced by a significant minority of participants.

Oliver *et al* (2002) and Lennox *et al* (2005) discuss the importance of negotiation with wide networks of stakeholders in order to conduct successful RCTs in this population. This network must include local service providers, health and social care organisations. Lai and colleagues (2006) claim that the attitudes of research ethics committee members to people with learning disabilities may affect clinical research. However, it is encouraging that, at least in the UK, there is ample guidance for research ethics committee members and researchers alike on how to consider ethical issues involving incapacitated adults in research (National Patient Safety Agency, 2007). Future researchers conducting RCTs in learning disabilities should seize the opportunity to understand the conditions of stakeholder research participation, and try to improve the ways in which they communicate study purpose and methodology. Such an approach would increase the engagement and social acceptance of much-needed clinical trials.

### Summary points

- ▶ Researchers have difficulty in conducting RCTs with people with learning disabilities.
- ▶ There is a lack of detailed evidence exploring the experiences of carers and service users with learning disabilities who participate in clinical trials.
- ▶ At least carers of people with learning disabilities appear to favour research and RCTs, but therapeutic misconceptions may affect informed choice in participation.

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### 7.3 Search terms for systematic review

1. (MENTAL\* near RETARD\*)
2. (MENTAL\* near HANDICAP\*)
3. (MENTAL\* near DISAB\*)
4. (MENTAL\* near DEFICIEN\*)
5. (MENTAL\* near IMPAIR\*)
6. (MENTAL\* near DIFFICULT\*)
7. (LEARNING near DISAB\*)
8. (LEARNING near DEFICIEN\*)
9. (LEARNING near DIFFICULT\*)
10. (DEVELOPMENTAL\* near DISAB\*)
11. (DEVELOPMENTAL\* near IMPAIR\*)
12. (DEVELOPMENTAL\* near DEFICIEN\*)
13. (DEVELOPMENTAL\* near DIFFICULT\*)
14. (INTELLECTUAL\* near DISAB\*)
15. (INTELLECTUAL\* near IMPAIR\*)
16. (INTELLECTUAL\* near DEFICIEN\*)
17. (INTELLECTUAL\* near DIFFICULT\*)
18. (AUTIS\*)
19. (ASPERGER\*)
20. (FRAGILE near X)
21. (DOWN\* near SYNDROME)
22. (WILLIAM\* near SYNDROME)
23. ((((((((((((((((((((((#1 or #2) or #3) or #4) or #5) or #6) or #7) or #8) or #9) or #10) or #11) or #12) or #13) or #14) or #15) or #16) or #17) or #18) or #19) or #20) or #21) or #22)
24. RCT\*
25. RESEARCH\*
26. (CLINICAL near TRIAL\*)
27. (RANDOM\* near TRIAL\*)
28. (MEDICAL\* near TRIAL\*)
29. (RANDOM\* near CONTROL\*)
30. (CLINICAL\* near CONTROL\*)
31. RANDOMI\*
32. (RANDOM\* near ALLOCAT\*)
33. (((((((((#24 or #25) or #26) or #27) or #28) or #29) or #30) or #31) or #32)
34. OPINION\*
35. EXPERIENCE\*
36. BELIEF\*
37. VIEW\*
38. ATTITUDE\*
39. BARRIER\*
40. OBSTACLE\*
41. HURDLE\*
42. (((((((#34 or #35) or #36) or #37) or #38) or #39) or #40) or #41)
43. (#23 and #33 and #42)

## 7.4 Ethics and research governance approval

### 7.4.1 Research Ethics Committee approval letter



#### South Essex Local Research Ethics Committee

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10 May 2006

Mr. Dan Robotham  
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Wolfson Building,  
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Dear Mr. Robotham

**Full title of study:** Stakeholder perceptions of the randomisation process for research in people with learning disabilities: a qualitative study in a clinical service

**REC reference number:** 06/Q0302/35

Thank you for your letter of 04 May 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair in consultation with the lead readers for this study.

#### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

#### Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

#### Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

#### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application	Version 5.1	27 March 2006
Investigator CV		27 March 2006
Protocol	Version 13.2	27 March 2006
Covering Letter		27 March 2006
Summary/Synopsis	Version 1.2	27 March 2006
Letter from Sponsor		21 March 2006
Peer Review		14 March 2006
Peer Review		31 October 2005
Interview Schedules/Topic Guides	Version 2.0	27 March 2006
Interview Schedules/Topic Guides	Version 2.2	27 March 2006
Interview Schedules/Topic Guides	Version 2.2	27 March 2006
Letter of invitation to participant	Version 3.0	17 March 2006
Letter of invitation to participant	Version 3	17 March 2006
GP/Consultant Information Sheets	Version 2.0	17 March 2006
Participant Information Sheet PIS Service Users	Version 4.1	26 April 2006
Participant Information Sheet PIS Professionals	Version 4.1	26 April 2006
Participant Information Sheet PIS Carers	Version 4.1	26 April 2006
Participant Consent Form Consent for Service Users	Version 4.1	26 April 2006
Participant Consent Form Consent for Participant	Version 4.1	26 April 2006
Participant Consent Form	Version 4.0	17 March 2006
Response to Request for Further Information		04 May 2006
Emails confirming permission to contact staff		
CV For Angela Hassiotis Supervisor	Version 1.0	
UCL Non-negligent harm insurance		22 March 2006

### **Research governance approval**

You should arrange for the R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research governance approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

<b>06/Q0302/35</b>	<b>Please quote this number on all correspondence</b>
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With the Committee's best wishes for the success of this project

Yours sincerely

  
Dr Kari Metcalfe

**Chair**

Email: [suzanne.emerton@essexsha.nhs.uk](mailto:suzanne.emerton@essexsha.nhs.uk)

## 7.4.2 Research Governance approval letter

South Essex Partnership 

NHS Foundation Trust

DMC.bc.let2146

31 May 2006

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Chief Executive: Dr Patrick Geoghegan OBE

Dear Mr Robotham,

**RE: QUALITATIVE INVESTIGATION OF A CHALLENGING BEHAVIOUR SERVICE**

Your proposal for the above research project was reviewed by the Trust's Research Governance Steering Committee (RGSC).

The RGSC has considered the research governance requirements and I am pleased to confirm that the RGSC has given their approval for this research project to be undertaken within the Trust.

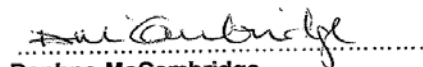
The RGSC also noted that you have received MREC approval and will ask that you inform the South Essex Local Research and Ethics Committee (SLREC) before you begin to recruit any participants and collect any data pertaining to your research. Contact details for SLREC: –

Suzanne Emerton  
9<sup>th</sup> Floor, Terminus House The High Harlow Essex CM20 1XA  
Tel: 01279 419312, Fax: 01279 694917

In addition, we would like to be notified when the project actually commences and when it is completed as we are required to add details of your project to the National Research Register, listing your name as the local contact point.

I hope all goes well with your research.

Yours sincerely,



**Daphne McCambridge**  
Deputy Director, Integrated Governance  
on behalf of the R&D Steering Group

[www.southessex-trust.nhs.uk](http://www.southessex-trust.nhs.uk)

Working in Partnership with Essex County Council,  
Thurrock Council and Southend Borough Council



## 7.5 Information sheets and consent forms

Please note, the text and pictures for the information sheet and consent form have been reduced in size. This is in order to fit the margins of the thesis.

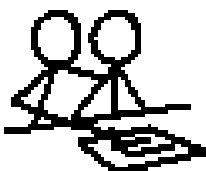
### 7.5.1 Service user information sheet

What do you think about being given help at random because of research?

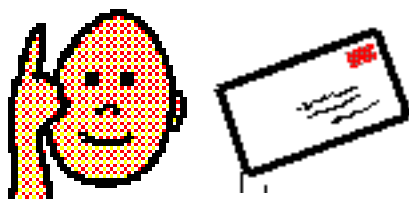
My name is Dan Robotham



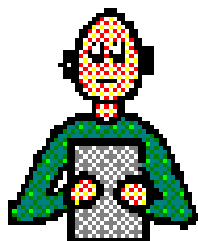
I am a psychologist



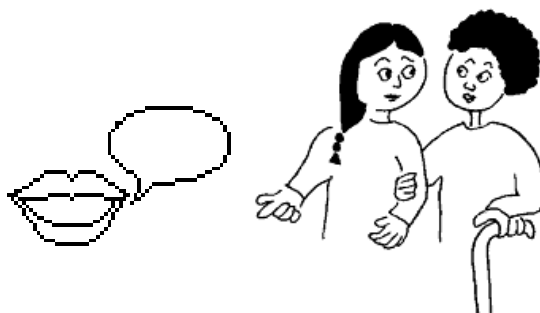
I am writing to ask if you want to help me



To help you understand this letter you can:



Ask someone to read it for you



Talk to your carer about it

**What is my work about?**



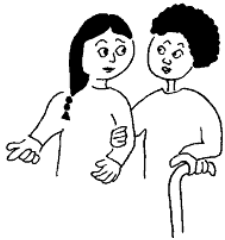
My work is about:

- Asking you what you think about research for people with learning disabilities

**Why do I want to see you?**



I want to talk to:



- People with Learning disabilities
- Carers who help you

**Do I have to take part?**



You can tell me "**Yes**" if you want to



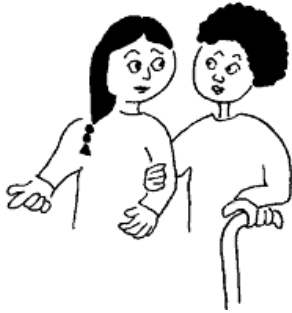
You can tell me "**No**" if you do not want to

If you say "**No**" you will be looked after the same as if you say "**Yes**"

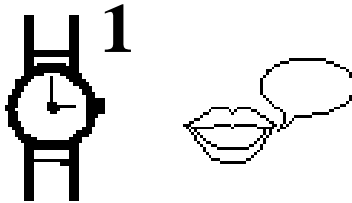
What will happen if I take part?



We will meet at your day centre, home, or at the learning disabilities base, whichever is best for you



You can bring someone to help you



The meeting will last no longer than 1 hour

I want to know what you think about research for people with learning disabilities



I will record the meeting to listen to later

What happens after the meeting?



I will not talk to anyone else about you. It is **confidential**...

...unless you tell me that you might harm yourself or someone else in future, then I will talk to your doctor.



I will never let anyone else listen to the tape of our meeting



If you want to talk to me please telephone me:  
My telephone number is – 0207 679 9587

Thank you for reading this.



Dan Robotham,  
Department of Mental Health Sciences,  
Wolfson Building,  
48 Riding House St,  
London W1W 7EY.

This research has been reviewed by the South Essex Local Research Ethics Committee

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REPLY SLIP



I am interested and would like Dan to tell me about it:

Name: \_\_\_\_\_

Contact Number: \_\_\_\_\_

Address: \_\_\_\_\_

---

Thank you very much

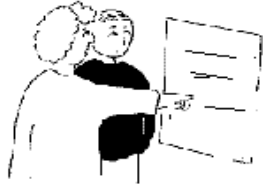


## 7.5.2 Service user consent form

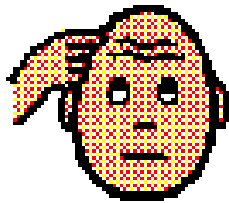
What do you think about being given help at random because of research?

**Yes**

**No**



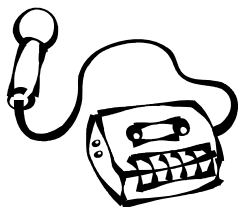
I have read the information sheet about the study  
(Version 4.2, created on 23 November 2006)



I can understand the things the information sheet told me



I was able to ask questions if I wanted to

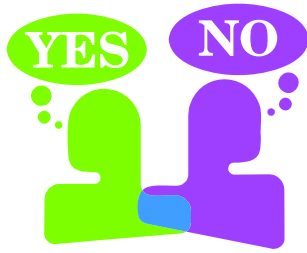


I understand that the meeting will be tape-recorded and the researcher may report what I say later (no-one will know it is you because your name will be hidden)



I want my doctor to be told





I understand that it is my choice to take part in this study

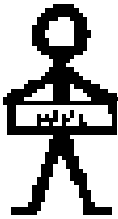


I understand that I can say **No** at any time if I want to stop



**It will not change the care I get**

---



Name: \_\_\_\_\_



Date: \_\_\_\_\_



Signature: \_\_\_\_\_

Researcher's signature: \_\_\_\_\_

---

## 7.6 Interview schedules

### 7.6.1 Interviews with carers

*“Thank you for making time to talk to me today. I’d like to discuss your ideas and experiences around research in Learning Disabilities. You are welcome to ask any questions about my research after today’s discussion. There are no correct answers to my questions; your views are relevant whether they are positive, negative, or indifferent. I have asked your permission to tape record the interview. Your contributions will be made anonymous and confidential; I am the only person who will listen to this tape.”*

What do you know about the Behaviour Therapy Team?

How much contact have you had with them?

Who was involved in the referral?

What did you expect from the referral?

Did X need the referral at the time?

Has X received any extra input in the last 12 months?

How helpful was the input? **OR** Would you have liked extra input?

Do you have any opinions about research?

Have you ever taken part in research?

Are you aware of the research of the Behaviour Therapy Team?

What did you expect from this research?

Why do you think this research was done?

What influenced your decision to take part?

Did you speak to anyone else about it?

Has the research made it easier or more difficult to access the behaviour therapy team?

Have you looked elsewhere for help?

Would you seek help from the Behaviour Therapy Team again if you needed to?

How do you feel about research in learning disabilities?

Are there any specific issues?

How should research be approached?

How appropriate is it?

Are there any cases where it would be inappropriate?

Could you please tell me what the following words mean to you – ‘Research’, ‘Random’, ‘Trial’

*I’m going to stop the tape for a few moments whilst you read this research scenario. (present vignette)*

### VIGNETTE

How do you feel about this situation?

Is this fair?

Is this a good idea?

What do you think about the use of the computer in this situation?

Why do you think it was done like this?

Can you think of another way to decide?

Why do you think the research lasted six months?  
Why do you think this kind of research was done?

How acceptable is it for people to be unsure about the benefits of services?  
What about health professionals (doctors, nurses, etc). How certain should they be about service benefits?  
Do you think services need to be assessed?  
How do you think the service should be assessed?  
How acceptable is it to restrict participant's access to services for the purpose of research?  
Is this situation any different for people who have learning disabilities?  
How would you feel if X had been put into the 'other' group?  
How would you feel if this was a trial of a new drug rather than of a service?  
Who benefits from this situation here?

(if unmentioned) How should the issue of consent be approached?

We have talked about a lot of things today, you've said some important things. First of all you said that 'x', is that right?  
Also 'y' have I got that right? And finally 'z', is there anything you would like to add?

Please could you fill out this personal details form for me. (END)

### **7.6.2 Interviews with health professionals**

*"Thank you for making time to talk to me today. I'd like to discuss your ideas and experiences around research in Learning Disabilities. You are welcome to ask any questions about my research after today's discussion. There are no correct answers to my questions; your views are relevant whether they are positive, negative, or indifferent. I have asked your permission to tape record the interview. Your contributions will be made anonymous and confidential; I am the only person who will listen to this tape."*

What do you know about the Behaviour Therapy Team?  
How much contact do you have with them?  
Do you make referrals?  
What usually happens when you make a referral?  
Have you made any referrals recently?  
Who was involved?  
What would you expect from a referral?  
(Did X need the referral at the time?)  
(Has X received any extra input in the last 12 months?)  
(Would you have liked extra input?)

Do you have any opinions about research?  
Have you ever taken part in research?  
Are you aware of any research that is going on locally?  
Are you aware of the research of the Behaviour Therapy Team?

What did you expect from this research?  
Why do you think this research was done?  
Has it changed your opinion of the Behaviour Therapy Team?  
Has the research made it easier or more difficult to access the Behaviour Therapy Team?  
Are you still making referrals to the Behaviour Therapy Team?  
Have you looked elsewhere for help?  
Will you make referrals to the Behaviour Therapy Team in the future?

How do you feel about research in learning disabilities?  
Are there any specific issues?  
How should research be approached?  
How appropriate is it?  
Are there any cases where it would be inappropriate?

Could you please tell me what the following words mean to you – ‘Research’, ‘Random’, ‘Trial’  
*I'm going to stop the tape for a few moments whilst you read this research scenario. (present vignette)*

#### VIGNETTE

How do you feel about this situation?  
Is this fair?  
Is this a good idea?  
What do you think about the use of the computer in this situation?  
Why do you think it was done like this?  
Can you think of another way to decide?  
Why do you think the research lasted six months?  
Why do you think this kind of research was done?

How acceptable is it for people to be unsure about the benefits of services?  
What about health professionals (doctors, nurses, etc). How certain should they be about service benefits?  
Do you think services need to be assessed?  
How do you think the service should be assessed?  
How acceptable is it to restrict participant's access to services for the purpose of research?  
Is this situation any different for people who have learning disabilities?  
How would you feel if a person you cared for had been put into the ‘other’ group?  
How would you feel if this was a trial of a new drug rather than of a service?  
Who benefits from this situation here?

(if unmentioned) How should the issue of consent be approached?

We have talked about a lot of things today, you've said some important things. First of all you said that 'x', is that right?

Also 'y' have I got that right? And finally 'z', is there anything you would like to add?

Please could you fill out this personal details form for me. (END)

### 7.6.3 Interview with service users

*Hello, my name is Dan, I'm a researcher. Today I want to talk to you about research. I am going to tape-record our conversation. This will make my work much easier. I will never play this tape to anybody else.*

Do you know what the Behaviour Therapy Team is?

Have you seen anyone from the Behaviour Therapy Team?

What was the name of the person you saw?

How often have you seen X?

Have you found them helpful?

Did you want them to help you?

Do you know what 'research' is?

Can you tell me what it means to you?

Have you ever helped in research?

Were you helping me do research on the Behaviour Therapy Team?

Do you like helping with research?

Can you think of a reason why research is done?

How did you feel when you decided to help me before?

Did you want to help?

Did you speak to anyone else about it?

Has research made it easier or harder for you to see the Behaviour Therapy Team?

How do you feel about research in learning disabilities?

Are there any specific issues?

How should research be approached?

How appropriate is it?

Are there any cases where it would be inappropriate?

What do you think about doing research with people who have learning disabilities?

Do you think it is a good thing or a bad thing?

What should people like me think about when we do research?

What can we do when we want to talk to someone who does not speak?

Is there anyone else you think we should speak to?

Could you please tell me what these words mean to you – 'Random', 'Trial' (present vignette) *I'm going to stop the tape for a few minutes while you read this story.*

### VIGNETTE

Do you recognise this at all?

Can you see what the researcher is doing?  
What has she done here?  
Is there anything you like about it?  
Is there anything you don't like about it?

How many people were helping the researcher?  
*There were 20 people helping the researcher...*

How many people saw the Behaviour nurse?  
*10 people saw the Behaviour nurse...*

Is this a good idea?  
Is it fair?

How did she decide who saw the Behaviour nurse?  
What did she do?

*She pulled the names out of a hat...*

Is this a good idea?  
Is this fair?

Can you think of another way?

Why didn't everybody get the new service?

Could she still see if the new service was helping?

Do you know what the researcher did it this way?

Do you get any services at the moment?

Do you like the services you get?

Would you like people to try and find out how good your services are?

Is it OK for researchers to try and find this out?

How would you feel if researchers tested your services?

Should she test the service in this way, or not?

How do you think services should be tested?

*People might do this kind of research when they are not sure if a new service (or tablet) is helping*

How do you feel about this kind of research?

Can you think of a good thing about it?

Can you think of a bad thing about it?

Is it OK to do this kind of research with people who have learning disabilities?

Is it OK to do research like this to test new tablets (instead of a new service)?

Who benefits here?

We have talked about a lot of things today, you've said some important things. First of all you said that 'x', is that right? Also 'y' have I got that right? And also 'z', is there anything you would like to add?

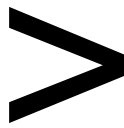
Please could you fill out this form for me? (END)

## 7.7 Pictorial vignette

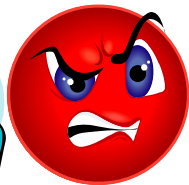
Note, the original version of this vignette was in colour



some people get angry often



The community **nurse** tries to help them



a **behaviour nurse** also tries to help them



the behaviour nurse is a **new service**



a researcher wants to see if the new service **helps** people who are angry





20

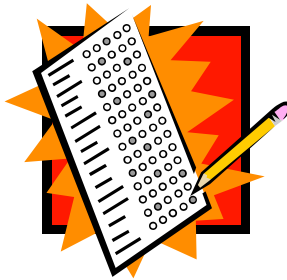
she asks people to help her  
20 people agree to help her



these people all want  
help for their **anger**

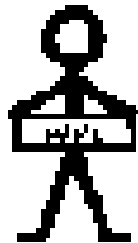
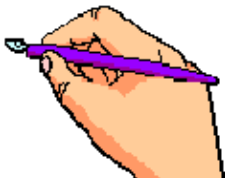


the researcher asks them  
how angry they feel



before

The researcher  
writes it in her **notes**,  
this is **before** they  
see a nurse



she writes the names of all 20  
people on small pieces of paper

20



then she puts the names into a hat

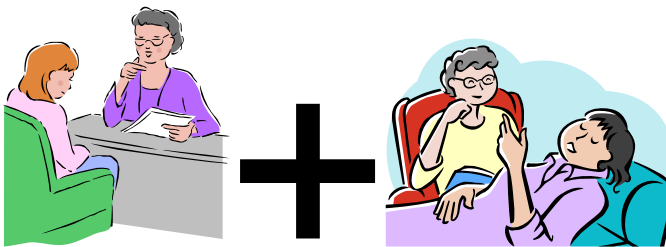
10



she picks 10 names from the hat

group A

these people are in **group A**



**group A** will see the community nurse

they will see the **behaviour nurse** too

10



she picks the other names out of the hat

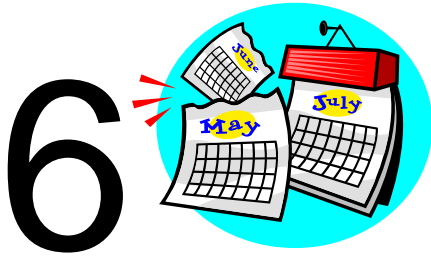
group B

these people are in **group B**

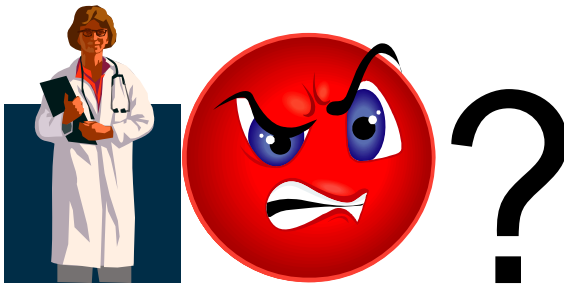


group B will see the community nurse

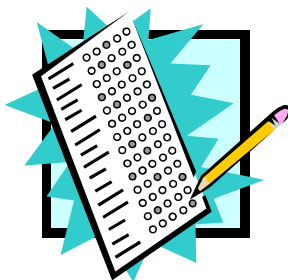
but they will **not** see the behaviour nurse



6 months later...



the researcher asks the 20 people how angry they feel



after

the researcher writes it in her **notes**, this is **after** the nurse has seen them



the researcher looks at her notes

she can see if the nurses have helped people with their anger

she compares her notes for **group A** and **group B**

group A OR group B



she can see how much the **behaviour nurse** has helped



the researcher has **tested** the new service

## 7.8 Participant profiles

Participant cases are presented in alphabetical order. Several key words and phrases are used within these profiles; the 'trial period' refers to the amount of time between an RCT participant's baseline assessment and six-month follow up assessment. This period is significant because it bound RCT participants to allocation group; that is either to the intervention or to the control group. The Behaviour Therapy Team (BTT) refers to the intervention team.

*Alice* – Works as a professional therapist within the local intellectual disability community. She works directly with service users, and also manages other staff members within her division. Referrals to her and her team are taken from other members of the intellectual disability service as and when required. She has worked with this population for over 20 years, and holds postgraduate qualifications. She demonstrates an interest in research and a desire to improve her knowledge of the subject, and she has sat on research steering committees. Still, her knowledge of the REBILD trial is limited by her working context, she is aware of the RCT, but her own work has not been directly affected by it.

*Andrea* – A nurse who was working within the intellectual disability services. She was in the process of completing her nursing degree at a local university. She has worked with the intellectual disability services in the local area for five years. During the duration of the REBILD trial she had not made any referrals for participants. However, she is aware of the RCT from discussion with colleagues. She has gained knowledge of research through her nursing degree, and has some experience of conducting research for her dissertation.

*Andy* – A nurse who has worked within local intellectual disability services for nearly 20 years, and has more than 30 years experience of working with people with intellectual disability. Unlike many of the other nurses he does not possess a university degree. He appears enthusiastic about research and has a limited awareness of the REBILD trial. He does not feel as though the RCT has affected his work patterns. However, one of the service users on his caseload was recruited as a participant for the RCT, and he continues to see this person

on a regular basis. This participant was randomised to the intervention group and received behaviour therapy during the trial period.

*Angela* – A support worker within local intellectual disability services. She provides input for people who have mild intellectual disability to help them with their everyday lives. She has nearly 20 years experience of working with people with intellectual disability, and has been in the present post for 14 years. Prior to this, she worked in a large local institution before it was closed down. She has no formal qualifications and has never conducted any research. She was not aware of the REBILD trial prior to the interview, since it has not affected any of the service users on her caseload. She is able to relate to the trial through her own personal experiences of participating in other clinical research.

*Anna* – The mother of a person with intellectual disability, who was referred to the BTT for displaying challenging behaviours. The service user was randomised to the intervention group and received 20 hours input during the trial period. During this time the service user also received input from psychiatric nursing. Anna acted as the primary respondent on behalf of the service user throughout the assessment interviews of the REBILD trial. She gave assent for the service user to participate in the RCT, since this person had been diagnosed with moderate intellectual disability and was judged to have reduced capacity to provide informed consent.

*Beatrice* – A manager at a day centre. She has 15 years experience of working with people with intellectual disability. One of the regular attendees at the day centre was referred to the BTT and recruited as a participant in the REBILD trial. Beatrice negotiated with the service user's legal guardian to gain permission to participate, and also acted as the primary respondent on behalf of the service user throughout the research assessments. Beatrice herself had known the service user for over seven years. The service user was randomised to the intervention group and received 11 hours of input during the trial period, had no input from psychiatrists, but regular visits from a psychiatric nurse. Aside from the REBILD study, Beatrice has prior experience of acting as a participant in a genetic research study.

*Carla* – A nurse with six years experience of working within intellectual disability services. Carla made referrals for several service users to the intervention team during the trial period. Of these participants, three were randomised to the intervention group and one was randomised to the control group. Additionally, she supported two service users during baseline and follow-up assessments. Sometimes she was providing input and acting as a proxy respondent. She has had little previous experience with research.

*Catherine* – An occupational therapist working within local intellectual disability services. She has been working in the local area for five years, and has four years experience of working with people with intellectual disability. She has gained some familiarity with research through her undergraduate degree. She is aware of the RCT, but her role has not been affected much by it.

*Charlotte* – A nurse in local intellectual disability services. She has 18 years experience of working with this population and has worked within the local area for 14 years. Her postgraduate nursing degree has given her some experience in research. She is aware of the RCT, and made one referral to a CBT intervention within the BTT during the trial period. This referral was randomised to the control group.

*Christine* – A nurse working within the community services for people with intellectual disability. She has been in post for seven years and has ten years experience of working with this population. Her undergraduate degree has given her some knowledge of research. Therefore, she is aware of the RCT and feels that it has affected her work patterns. Three service users on her caseload were referred to the BTT and recruited to REBILD. Of these three participants, one was randomised to the control group and two were randomised to the intervention group.

*Craig* – A young man with mild intellectual disability. He lives independently in a tenancy accommodation, and has a full-time job. He was referred for intervention and enlisted as a participant in the RCT. He was randomised to the intervention group, but received minimal input from all intellectual disability services during the trial period. He has visited the psychiatrist once and had

one telephone call from his psychiatric nurse. He is aware of the intervention and has some prior experience with market research.

*David* – A member of the social work team within local intellectual disability services. He has been working with people with intellectual disability for 12 years and possesses vocational qualifications. He has heard a lot about the REBILD trial through discussions with other members of the team. His own workload has not been too affected by the RCT but he feels that it has affected the work of the team.

*Elaine* – A professional therapist and service manager working within mental health services in the local area. She has previous experience of working with people with intellectual disability and challenging behaviour. She has a large amount of research experience, and has attempted to conduct a clinical trial within this population in the past. The REBILD trial did not directly affect her and she made no referrals to the intervention. Most of her daily work lies in other fields outside of intellectual disability.

*Elizabeth* – A young woman with a diagnosis of mild intellectual disability. She lives independently and has had a variable employment history throughout the previous year. She has used local voluntary organisations but does not use day services. A psychiatric nurse referred her to the intervention team and she was recruited to the REBILD trial. She was randomised to the intervention group but had received no intervention during the trial period. However, she had psychiatric nurse input and made two visits to the psychiatrist. She was aware of the BTT through previous contact, and seems to have some understanding of research.

*Elsie* – The mother of a person with mild-moderate intellectual disability. The service user received a referral to the intervention and was recruited to the REBILD trial. Elsie acted as a proxy respondent for the service user throughout the trial period, and she is aware of the research trial. The service user was randomised to the control group. The intervention referral was later withdrawn through discussion between Elsie and other stakeholders. However, she maintained regular contact with the psychiatric nurse, and she had seen the



psychiatrist twice. She also has regular contact with family members who provide some respite.

*Emily* – As a paid carer, Emily has worked professionally with people with intellectual disability for 20 years, and she also has relatives with intellectual disability. She provides daily care for a service user with mild intellectual disability, who she has known for about four years. This service user had received a referral for behaviour intervention and was recruited to the REBILD trial. The service user consented to participate, but Emily acted as a proxy respondent on behalf of the service user throughout the trial period. The service user was randomised to the intervention group and received 20 hours of input from the intervention team during the trial period, there was no psychiatric nurse input but they visited the psychiatrist once. Emily was familiar with the intervention team because the service user had used BTT services previously.

*Eva* – A social care professional working for local intellectual disability services. She has been working with people with intellectual disability for two years. Her postgraduate degree has given her some research knowledge, and she is aware of the BTT intervention because she has made referrals to them in the past. However, she has not made any referrals within the trial period. Therefore, she is largely unaware of the RCT until presented with the vignette.

*Fiona* – A young woman with mild intellectual disability living with her family. She is employed part-time and attends intellectual disability services regularly. She was referred for intervention and enlisted in the REBILD trial, but she was randomised to control group. Her intervention began following the six-month assessment and she was aware of the intervention process. During this time, she kept regular appointments with her psychiatric nurse, but had no recent input from a psychiatrist. She acted as a respondent during the trial assessments and was aware of the research. This interview was recorded using written notes because Fiona was uncomfortable about being recorded on the Dictaphone.

*Greg* – A clinician who has been working with people with intellectual disability for seven years. He has postgraduate medical education and knowledge of

clinical research. He does not make referrals to the intervention team so the trial has not affected his work greatly. However, he had been working with several RCT participants and was aware of the RCT since the beginning.

*Hannah* – A social care professional who has worked within local intellectual disability services for seven years. She holds undergraduate degrees in social sciences and has experience of conducting research at this level, and professes an interest in research. She has not made referrals to the BTT during the study period, but has referred to other similar services. She was aware of the RCT, but her knowledge of it was limited.

*Helen* – A manager of a residential care home for people with intellectual disability. She has worked with this population for seven years, has also completed an undergraduate degree and has conducted research projects at university. A service user in her care was referred for intervention and recruited onto the RCT. The service user was randomised to the intervention group and received 31 hours of intervention over the trial period, along with one psychiatric appointment. Helen acted as a primary respondent on behalf of the service user during the trial period. She and several other members of staff were involved in supporting the service user to provide consent to participate in the RCT.

*James* – A social care professional for the intellectual disability service who has been working with people with intellectual disability for over two years. He has completed an undergraduate degree in social work. James was consulted as a stakeholder during the consent process for two RCT participants on his caseload. He is aware of the RCT but he does not think it has affected his work.

*Janice* – A manager of social services for people with intellectual disability within the local area. She has seven years experience of working with this population. She has a postgraduate qualification and knowledge of research methodology. She does not make referrals to the intervention team and was only aware of the RCT through liaising with co-workers.

*Jean* – The mother of a person with complex needs and severe intellectual disability. The service user received an intervention referral and was enlisted in

the RCT with parental assent, prior to the implementation of the Mental Capacity Act in August 2005. The service user was randomised to the control group but did receive intervention from other services during this period. Jean has experience with behavioural interventions in the past, and her child has used these services previously. Jean acted as the primary respondent throughout the three assessments, the service user lacked capacity to provide informed consent to take part. Additionally, Jean received regular telephone input from her psychiatric nurse about her child's situation, and she visited the psychiatrist once.

*John* – A nurse with over thirty years experience of working within the intellectual disability field, who has worked in the local area throughout this period. He holds a postgraduate degree and has conducted research with this population in the past. He has experience of research methodology and he has a good understanding of clinical trials. He is aware of the RCT and it has affected his work patterns directly.

*Julie* – A nurse who has over thirty years experience of working with people with intellectual disability. She has a postgraduate degree in nursing and is familiar with research. She made one referral to the intervention team during the trial period, and this person was randomised to the intervention group. She is familiar with the RCT and has liaised with the research team on several occasions.

*Lisa* – A young woman with mild intellectual disability. She lives at home with her family and was employed. She was referred for intervention, recruited to the RCT and was randomised to the intervention group. During the trial period she received four two-hour intervention sessions. However, she had received no input from the psychiatric nurse, and visited the psychiatrist once. She is aware of the research and helped respond to research interviews throughout the trial period, with assistance from her parents.

*Louise* – A nurse who has been working in the local area for nine years. She now specialises in providing interventions for people with intellectual disability. She possesses vocational nursing qualifications and has an interest and

awareness of research methodology. She was aware of the RCT because it had affected the work of some of her colleagues.

*Lucy* – A manager of a residential care home for people with intellectual disability. She has been working with people with learning disabilities for six and a half years. She acted as proxy respondent for two service users during the trial, and provided assent for both of them to participate in the RCT. Both service users had moderate to severe intellectual disability and were unable to provide informed consent. Both service users were randomised to the intervention group and received input during the six month period, but neither service user received any input from psychiatric nursing or psychiatry at this time.

*Marie* – A nurse in intellectual disability services. She has over twenty years experience of working with this population. She holds a postgraduate degree but claims only limited experience with research. She was aware of the RCT through regular contact with the research team, and claims that it has affected her work patterns.

*Mark* – A nurse in intellectual disability services. He has over twenty years experience of working with this population. He has a postgraduate degree and is aware of the RCT through regular contact with the research team. He claims that the RCT has affected his referral patterns. He was the named nurse for one participant during the trial, and this participant was randomised to the control group. He has also maintained regular contact with several other RCT participants.

*Martin* – A middle-aged man with mild intellectual disability who lives with his family. He has good verbal communication but limited reading and writing skills. He had been referred for intervention for behavioural issues and recruited into the RCT. He was randomised to the intervention group and received 14 hours of intervention, though he had no input from psychiatry or psychiatric nursing during the trial period. Consultation with family members and social workers was required to recruit Martin successfully. He is aware of the intervention, but has difficulty understanding research concepts.

*Mary* – A nurse who has worked in the intellectual disability field for 11 years. She holds an undergraduate degree has been aware of the RCT from the beginning. She also seems positive about research and has provided input for several participants during the RCT.

*May* – A nurse within intellectual disability services, she has worked in the field for over thirty years and possesses A-level equivalent qualifications along with vocational nursing qualifications. She has made several referrals to the intervention during the study period, and is aware of the RCT and the randomisation procedure. She believes that the RCT has affected work patterns for her and her colleagues.

*Mike* – A middle-aged man who was believed to have mild intellectual disability. This was later reclassified to moderate intellectual disability after the RCT and interview had been conducted. He has lived in a residential placement for 12 months, sharing with two other residents. Mike was having difficulty settling into his new home and a referral was made to the BTT, he was then enlisted into the RCT with the aid of his carer. At the time he regularly attended day and evening services for people with intellectual disability. Over time, he settled into his surroundings and his behaviours became less of a problem. He was randomised to the control group and received no input during the trial period. After the trial period his referral was cancelled due to improvements in his behaviour. He received no input from psychiatric nurse during the trial period, and visited the psychiatrist once. Mike seems unaware of the RCT but appreciates interacting with other people.

*Miranda* – A manager of a residential care home for people with intellectual disability. She had been working in this field for over 20 years, and is also a trained nurse. One of her clients, Mike, was referred for intervention due to behavioural problems. Miranda assisted Mike during the RCT assessments, helped him complete questionnaires and encouraged him to provide consent to participate. Mike was randomised to the control group and received no input during the trial period. After the trial, Mike received no further input due to improvements in his behaviour over time. The only input they received for Mike

during this period was one visit to the psychiatrist. Miranda is aware of the RCT and appears to have found it frustrating.

*Natalie* – A social care professional within the intellectual disability service. She possesses social care qualifications, and has worked with people with intellectual disability for 15 years. She expresses an interest in research and service development. She has a professional relationship with the intervention team and makes referrals occasionally. Still, she does not appear to know about the RCT.

*Nicholas* – A social care professional within intellectual disability services, with 30 years experience of working in the field. He has not had direct contact with the BTT during the trial, but has made referrals in the past and is aware of their work. Nicholas has an undergraduate degree and has conducted research with this population in the past, and relates to some of the problems he encountered. He knew nothing about the RCT before being approached for the interview.

*Oliver* – A professional service manager for intellectual disability services within the local area. He has been working in the area for 20 years and has been working with this population for 30 years. He is educated to postgraduate level, and supports clinical research within the local area. He is aware of the RCT because he was involved in research planning, but has little contact with service users. He appears optimistic about the future of services for people with intellectual disability.

*Patricia* – The mother of a service user with mild intellectual disability and challenging behaviour. The service user was referred for intervention by a social worker and recruited for the RCT. Following this, the service user was randomised to the intervention group and received 14 hours of intervention. They received no input from community nursing or psychiatry during the trial period, but continued to receive input from a social worker. Patricia assisted the service user with consent and assessment during the RCT, and occasionally acted as a proxy respondent. She appears positive about research and feels that it can help people with intellectual disability in the future.

*Philippa* – A support worker for people with intellectual disability. She has worked with this population for over twenty years. She had a close relationship with a service user who was referred for behavioural intervention. This service user had sufficient capacity to provide informed consent, but Philippa acted as a proxy respondent assisting the service user with assessments. Consultation for service user consent also involved the service user's mother. During the trial period the service user had been relocated twice, and was experiencing difficulties. The service user was randomised to the control group but received some input from the intervention due to her urgent situation and living arrangements. The community nurse also provided regular input for this service user. Philippa did not seem to relate to the RCT until presented with the vignette.

*Rebecca* – A nurse for an intellectual disability service. She has been working locally for two years and has been working with this client group for 19 years. She holds a postgraduate degree and is familiar with research. She has made referrals to the intervention team since the RCT started. The majority of these referrals were allocated to the control group, which she has found difficult.

*Sally* – A trained nurse and manager of a residential nursing home for people with intellectual disability. She has worked in the intellectual disability field for 11 years. One of the residents in the residential nursing home was experiencing some difficulties, and a referral was made to the BTT. The service user was then recruited for the RCT. Sally and several other staff members were involved in the consent and recruitment process, and she acted as proxy respondent during the trial period. This service user was randomised to the control group and received no input after the trial because the referral was deemed inappropriate. However, five appointments with the psychiatrist were made. Sally appeared interested and knowledgeable about research.

*Sandra* – The mother of a service user with mild intellectual disability who was referred to the intervention team. The service user was referred for intervention and randomised to control group. Intervention with this service user began shortly after the trial period. Sandra helped the service user to provide informed

consent to participate in the RCT. She also assisted the service user with assessments, and acted as a proxy respondent where necessary.

*Sarah* – A support worker at a day centre for people with intellectual disability. She has 17 years experience of working with this population. She provided daily support for a service user who was having some difficulties at the day centre. This service user had severe intellectual disability, and she had known them for nearly 14 years. A referral to the BTT was made, and the service user was recruited into the RCT. Recruitment was done through consultation between Sarah and the service user's mother. The service user was randomised to the intervention group and received 27 hours of input. Sarah provided proxy responses for the service user on two occasions during the trial period. In addition, this service user had two psychiatric appointments and a small amount of input from the local psychiatric nurse. Sarah was aware of the research but did not initially appear to understand the RCT.

*Sayeed* – He has been working in the local area for six years, and has 25 years experience of working in intellectual disability services. He has a medical degree, with knowledge and experience of clinical research. He was aware of the RCT, and is interested in the local service development for people with intellectual disability. He was providing input for nearly a third of the RCT participants, and liaises with psychiatric nurses from the local services.

*Sue* – A paid carer and manager of a residential home for five people with intellectual disability. One of the residents had displayed challenging behaviour and was referred for intervention. Sue provided assent for the service user to be enlisted in the RCT. She also acted as a proxy respondent for this service user throughout the trial period. This service user had moderate intellectual disability and problems with memory, and Sue had known the service user for just over a year. This service user was randomised to the intervention group and received over 50 hours of observation during the trial period. Additionally, the service user had two domiciliary visits from the psychiatrist, but no input from the local psychiatric nurse. Sue appears knowledgeable about research, and has some previous experience as a research participant.



*Theresa* – A retired mother of a person with intellectual disability. The service user was referred to the BTT and randomised to the intervention group. Over the RCT assessment period the service user received four 2-hour sessions of intervention. Theresa assisted the service user throughout the trial period, though the service user had sufficient capacity to provide informed consent. Theresa also acted as a proxy respondent where appropriate and necessary. She did not have any prior research experience before taking part in the RCT.

*Thomas* – A paid carer at a residential home for people with intellectual disability. Thomas has one year experience of working with this population. Thomas acted as a proxy respondent for a service user within the residential care home who had displayed challenging behaviour. This service user had severe intellectual disability and limited verbal communication, and could not provide informed consent to participate. Assent for the service user to participate was given by the home manager, and Thomas provided consent for his own participation in REBILD. This service user was randomised to control group and received no input during the trial period. However, other service users within the residential care home received some intervention input over the course of the RCT. Following the trial period he felt that intervention was unnecessary and that many of the problems with this service user had been sorted out internally. The service user saw the psychiatrist three times during the RCT assessment period, but had no recorded input from the psychiatric nurse. Thomas has a university undergraduate degree and is knowledgeable about research.

*Tracey* – The manager of a residential home for people with intellectual disability. She has worked with this population for 14 years across different areas of the country. Two service users from this residential home were referred to the BTT, and both were enlisted into the RCT. Tracey was consulted during the consent process for both of these service users, and she acted as a proxy respondent for one service user throughout the trial period. She had known this service user for about one year, and they had severe intellectual disability and little verbal communication. This service user was randomised to receive intervention, and received 29 hours of input. The service user also had regular input from the psychiatric nurse, and one visit to the

psychiatrist. This service user became much better adjusted to her environment during the trial period. The second service user from Tracey's residential home was randomised to the control group and received no input from the BTT. This service user was moved to another residential placement during the RCT assessment period.

*Trudy* – The mother of a person with moderate intellectual disability. Trudy receives domiciliary help for the service user on several days per week. The service user was referred to the BTT by the psychiatric nurse, and recruited into the RCT. The service user was unable to provide informed consent to participate without Trudy's assistance and permission. The service user was randomised to the control group and received no input from the BTT during the trial. However, they received considerable input from the psychiatric nurse during the trial period, and had two visits to the psychiatrist. Trudy acted as the proxy respondent throughout the trial period. She had no previous experience with research and was not knowledgeable about the RCT.

## 7.9 Coding framework

Level 1	Level 2	Level 3	Level 4
Work environment	Procedures Organisation Job roles Changes Resources	Waiting lists Specialisms Skills and training Morale Teamwork	
	Intervention	Expectations Preferences Equipoise	
Client problems	Need Help	Coping Problem solving Seeking help	
	Emergencies Duration Motives Advocating/consent Relationships Carer feelings Clients		
Stakeholders		Comorbidity Ability Environment Societal disadvantage Client feelings Similarity and differences	
Medication	Drug effects Outcomes and benefits Awareness General research		
Research		Need Interest Positive/negative Previous experience Information sharing Purpose	Practicality Timeline Remit of RCT Progress Assessment Investigation Understanding Communication Involvement Accuracy Individuality Complexity Difficulties Safety Safeguards
	Issues	Interaction	
		Practicalities	
		Ethics	
	RCT Approach	Personal or impersonal	

Positive or negative  
Understanding RCT  
Prioritisation or  
randomisation  
Subjective or objective  
Easy or difficult  
Involved or detached  
Impact of RCT  
Motivation to participate  
Sample  
Semantics  
Pointless or useful  
Making comparisons  
Hypothetical or practical  
Fair or unfair  
Media influence  
Social or medical  
Credibility or bias  
Methods

Questioning  
Alternative  
approaches