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STUDY PROTOCOL
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A multi-centre phase 3 Cluster randomized controlled trial of a manualized anger management intervention for people with mild to moderate learning disabilities

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Please contact the Trial Coordinator for general queries and supply of trial documentation

Queries:

Queries

All queries should be directed to the Trial Manager who will direct the query to the most appropriate person

Serious Adverse Events

SAE reporting

Where the adverse event meets one of the serious categories an SAE form should be completed by the clinical P and faxed to the Trial Manager within 24 hours upon becoming aware of the event. (See sections 10 for more details)

Fax Number: 02920 687 612

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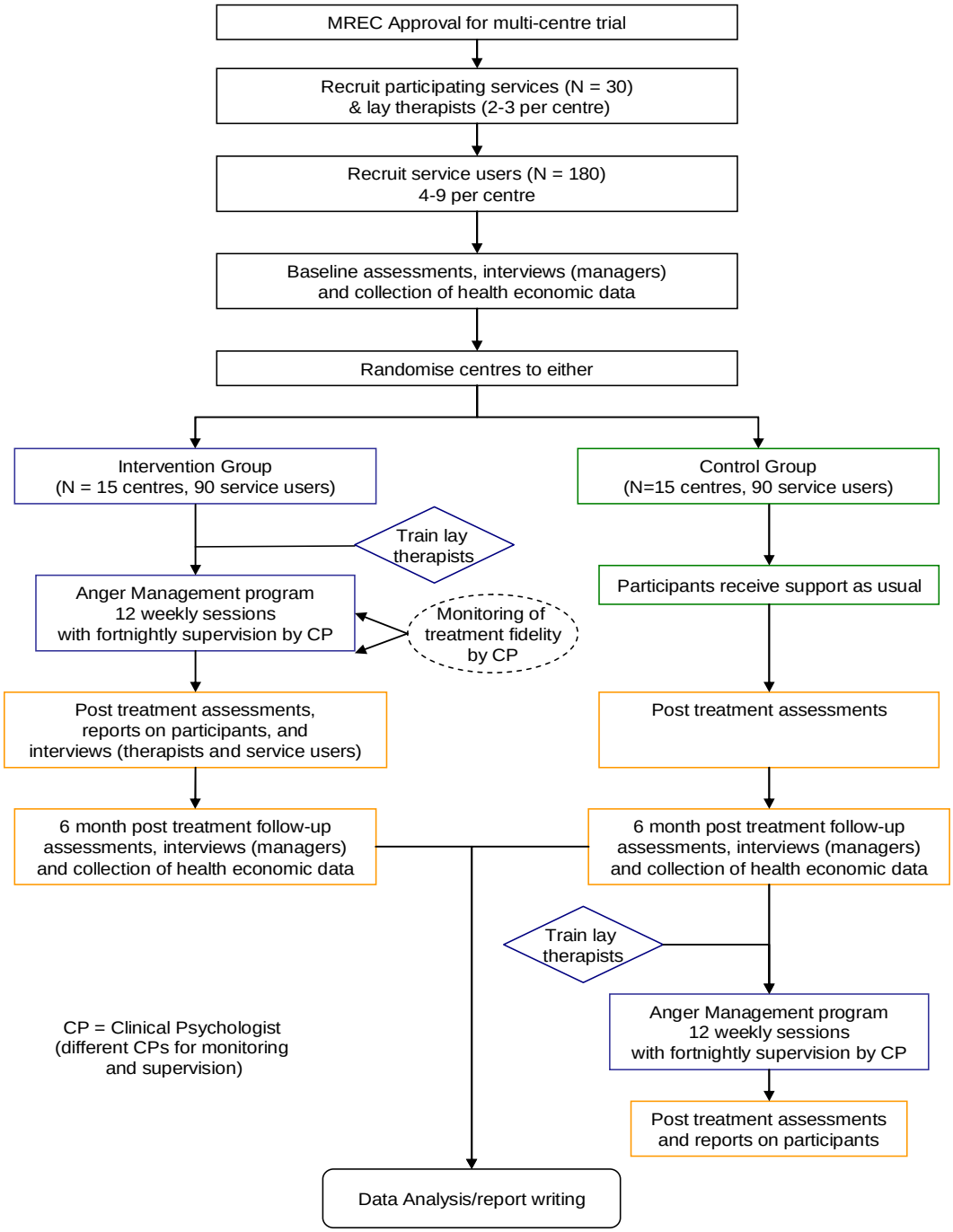
Glossary of abbreviations

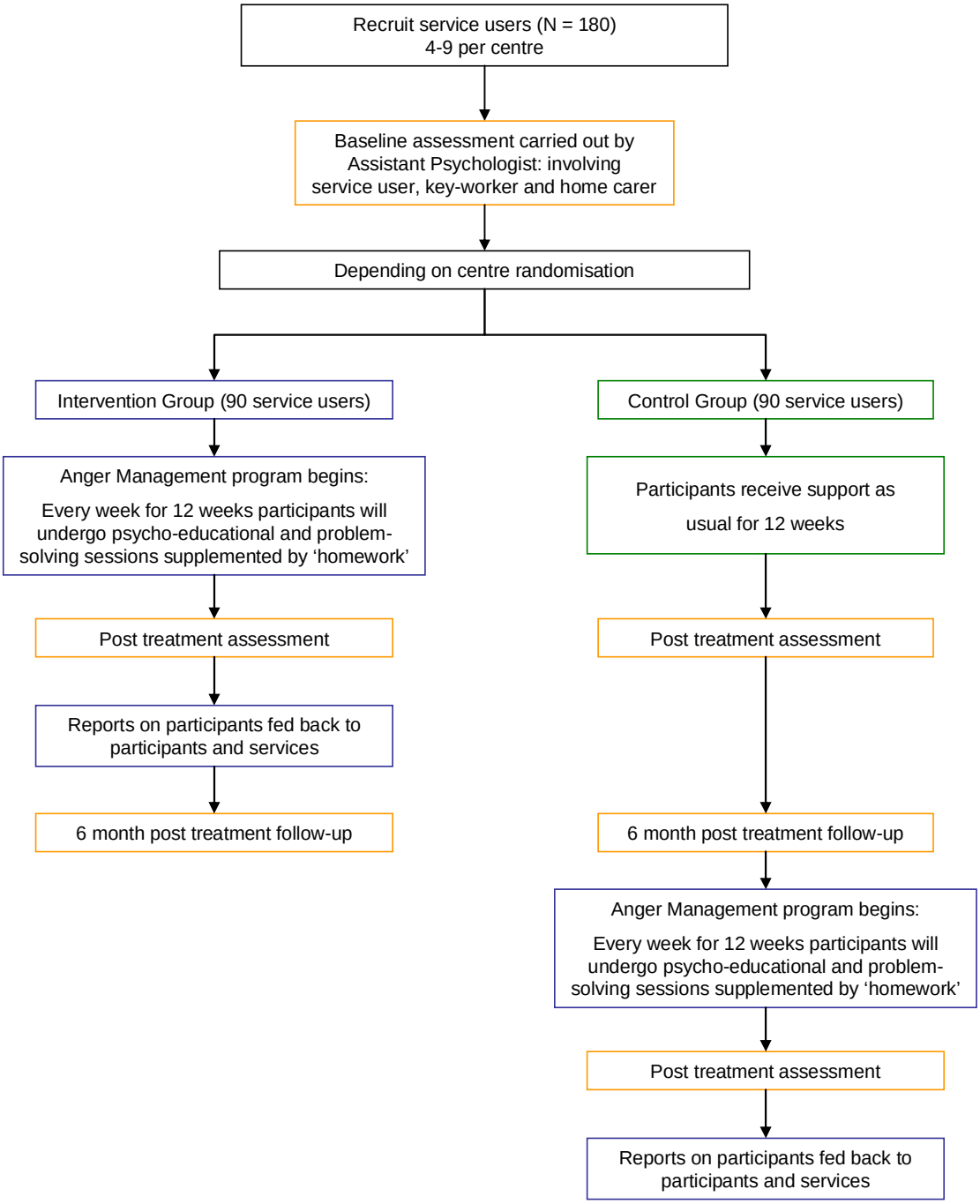
ABC	Aberrant Behavior Checklist
AE	Adverse Event
AP	Assistant Psychologist
BPVS	British Picture Vocabulary Scale, 2nd edition
CACE	complier adjusted causal effect
CBS	Controllability Beliefs Scale
CBT	Cognitive behaviour therapy (
CF	Consent Form
CI	Chief Investigator
ComQoL-ID	Comprehensive Quality of Life Scale - Intellectual Disability
CP	Clinical Psychologist
CSRI	Client Service Receipt Inventory
CTC	Common Toxicity Criteria
CTU	Clinical Trials Unit
CU	Cardiff University
GCP	Good Clinical Practice
HTA	Health Technology Assessment
ICC	Interrelated correlated cluster
ICH	International Conference on Harmonization
IDMC	Independent Data Monitoring Committee
IEC	Independent Ethics Committee
IPA	Interpretative Phenomenological Analysis
ISRCTN	International Standard Randomised Controlled Trial Number
MOAS	Modified Overt Aggression Scale
PACS	Profile of Anger Coping Skills
PI	Provocation Index
PIS	Patient Information Sheet
POVA	Protection of Vulnerable Adults
QL (QoL)	Quality of Life
R&D	Research and Development
RCT	Randomized Controlled Trial
REC	Research Ethics Committee
RGF	Research Governance Framework for Health and Social Care
SAE	Serious Adverse Event
SAU	(support as usual:
SEWTU	South East Wales Trials Unit
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reactions
TA	Thematic Analysis
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
WASI	Wechsler Abbreviated Scale of Intelligence
WCLD	Welsh Centre for Learning Disabilities

1 Trial summary & schema

1.1 Trial schema



1.2 Participant flow diagram



1.3 Trial summary

Many people with learning disabilities find it hard to control their anger. This often leads to aggression, which can have serious consequences, such as exclusion from mainstream services and the need for potentially more expensive emergency placements. Anger management teaches people to recognize what makes them angry and learn skills that they can use to cope better with those situations. Several small studies of anger management groups for people with learning disabilities have shown promising results. All of the published studies have reported that people who take part in an anger management group show less anger at the end than people who are waiting for treatment, and they stay less angry for several months afterwards.

Anger management is usually taught by Clinical Psychologists. In this trial, the group therapy will take place in the services that the service users attend during the day, and the therapists will be staff in those services. A Clinical Psychologist will teach the staff how to work with a treatment manual. The manual was written for use by therapists who have never done this before. It gives full details of how to run each session of a 12-week anger-management course. A total of 180 service users with mild to moderate learning disabilities, who are identified as having problems with anger control, will be invited to take part in the study. They will be randomly allocated to one of two conditions, according to which day service they attend. Half of them will take part in staff-led anger management groups. The other half will be supported as usual by staff while they wait for treatment. At the end of the 12 weeks, there will be a three month follow-up period. Then the staff who work with the waiting-list groups will be taught how to use the manual, so that the waiting-list groups can also be offered anger management.

The project will take place in three different parts of the country. Altogether, there will be 15 treatment groups and 15 control groups, five treatment and five control in each region. We will train the staff how to use the manual; then, when the groups are running, we will check that staff are running them properly and if they are running well; and at the end, we will talk to staff about how they found it to run a group and if there has been any effect on the rest of their service. The main point of the project is that we will assess how well people are doing before and after they take part in an anger management group, and six months later.

We will measure how angry and aggressive people get and how well they cope with difficult situations, both in the service and at home, how they feel about themselves, and what they thought of the group. We will also find out if it costs less to support people after they have been part of an anger management group. We will do all this by talking to the service users themselves, their key-workers in the service, and their home carers.

2 Introduction

2.1 Background

2.1.1 Cognitive behaviour therapy

Cognitive behaviour therapy (CBT) is the treatment of choice for common mental health problems (Roth & Fonagy, 2004), and is recommended by NICE for this purpose. Widening access to CBT for people with mental health problems is seen as a major policy priority: the Department of Health has recently allocated £170 million to train 3600 CBT therapists (DoH/CSIP, 2007). However, people with learning disabilities are unlikely to benefit from this development, as their particular needs have not been identified within the current policy and the necessary research on effectiveness for this population is still at a rudimentary stage. It is only recently that CBT has been adapted for people with learning disabilities, and the evidence of its effectiveness in this population consists largely of case studies and case series. There is now a relatively large case-study literature describing successful outcomes for CBT in a variety of mental disorders (Lindsay, 1999; Hatton, 2002; Willner, 2005; Taylor et al., 2008). However, the evidence from controlled trials is sparse.

2.1.2 Anger in People with Learning disabilities

The most developed evidence base is in relation to anger. Anger is a frequent problem for many people with learning disabilities. Although anger can exist without being expressed aggressively, anger in people with learning disabilities is typically associated with verbal and/or physical aggression (Taylor & Novaco, 2005). Aggression is the main reason for an adult with a learning disability to be regarded as having severe challenging behaviour (Allen & Felce, 1999) and to be

referred for resource intensive intervention (Lowe et al., 1995). Left unchecked, aggression resulting from uncontrolled anger can lead to serious consequences, which include exclusion from services, breakdown of residential placements, and in extreme cases, involvement with the criminal justice system (Allen et al., 2007, Emerson et al. 2008; Mental; Mental Health Foundation, 2008). Aggressive behaviour can also have an impact on the psychological well-being of staff (Jenkins et al, 1997) and the quality of care they provide (Rose et al., 1998). Community services supporting adults with learning disabilities receive numerous referrals for anger problems: prevalence estimates for problem anger in the general population of people with learning disabilities vary between 11 and 27% (Rose et al., 2008). A review of recent studies of aggressive challenging behaviour reported that over half of the population of people with learning disabilities display some form of aggression (Benson & Brooks, 2008), and anger is highly prevalent in people labelled as having challenging behaviour: for example, Lindsay and Law (1999) reported that 60% of clients referred to a community service for people with learning disabilities and challenging or offending behaviours presented with clinically significant anger problems.

2.1.3 Anger Management Interventions

Challenging behaviour has traditionally been managed pharmacologically or behaviourally (Didden et al., 1999; Matson et al., 2000). However, following the demonstration that a CBT anger management intervention can decrease anger and aggression (Benson et al., 1986), the past 20 years has seen an increasing take-up of anger management as the first-line approach to these problems. With the exception of two small controlled trials in depression (McCabe et al., 2006; McGillivray et al, 2008), anger is the only psychological presentation in which controlled trials have been used to evaluate CBT interventions for people with learning disabilities. Several phase 2 trials have now been published in which CBT for anger has been compared with a waiting-list control condition. These include seven studies of anger management groups in community settings and one series of studies of individual treatment in a forensic setting (see Willner, 2007 for review), as well as a single study of individual therapy in a community setting (Rose et al., 2008). However, these typically have been relatively small studies, and have not used fully randomized allocation to treatment (Willner, 2007; Hassiotis & Hall, 2008). A recent Cochrane review of interventions for aggressive behaviour in people with learning disabilities (Hassiotis & Hall, 2008) identified only four studies suitable for inclusion, including one study of group-based CBT

for anger (Willner et al, 2002) and one study of individual CBT for anger (Taylor et al., 2005). The inclusion of these two anger studies in a review of aggression nicely illustrates the close relationship between anger and aggression, which, while conceptually distinct, co-occur to such an extent that the Cochrane review treated them as equivalent.

The published studies are fully consistent in reporting that anger interventions are effective in helping people with learning disabilities to manage their anger better, and that treatment gains are maintained at three or six-month follow up (see Willner, 2007 for review). There is also evidence that treatment gains generalize across settings. There is little information as to which are the crucial components of the intervention. However, one recent study reported a significant correlation between decreased anger reactivity and increased usage of anger coping skills, thus providing some evidence that the specific psycho-educational content of the anger management curriculum is intrinsic to its effectiveness (Willner & Tomlinson, 2007).

2.1.4 Anger Management programme

The technology to be assessed was optimized to take into account two factors that have been reported to improve the outcome of anger management in people with learning disabilities: higher receptive language ability and being accompanied to the group by a carer (Willner et al., 2002; Rose et al., 2005). Language ability is taken into account by maximising the use of non-verbal communication strategies and minimising the importance of verbal communication. In order to maximise the role of carers, staff who work with the participants on a daily basis will be trained to act as group leaders with the support of a treatment manual. Studies that have implemented anger management groups within learning disability day services, and involved day-service staff to deliver the therapy, have reported impressive outcomes, probably because staff routinely become familiar with the anger coping techniques that participants learn and are able to provide ongoing support outside the group sessions (Willner et al., 2005; Willner & Tomlinson, 2007). A manualized group intervention delivered by day-service staff has also been reported to improve depression in people with learning disabilities, relative to a waiting-list control group (McGillivray et al, 2008).

2.2 Rationale for the proposed study

The purpose of this study is to conduct the first phase 3 multi-centre trial to investigate formally how effectively staff working in services providing day activities for people with learning disabilities are able to use a therapy manual to deliver a CBT-based anger management intervention, following a brief training by a Clinical Psychologist. The study will incorporate a wider range of outcome measures than previous studies, and include an analysis of the cost consequences of delivering the intervention. The demonstration that service staff can successfully deliver anger management to people with learning disabilities would have very significant benefits in relation to the current policy of improving access to psychological therapies, by widening the pool of potential therapists, in addition to addressing more effectively an important and often unmet need of this vulnerable client group. Some scepticism has been expressed about whether it is feasible to undertake RCTs of psychological interventions for people with learning disabilities (Oliver et al., 2002). The successful implementation of this RCT would serve to allay these doubts and encourage further research to strengthen the evidence base for interventions to support this multiply-disadvantaged population. Moreover, the cost analysis will determine the extent to which delivering the intervention incurs resource inputs over and above treatment/support as usual and whether successful reduction of anger and aggression is associated with any change in subsequent resource use. In relation to this possibility, it is relevant to note that Felce et al. (2003) found that 26% of the variance in staff costs per person in residential services was associated with scores on the challenging behaviour measure (the Aberrant Behavior Checklist) which we are proposing to use as an outcome measure here.

The conclusion of the Cochrane review (Hassiotis & Hall, 2008) is highly relevant to the present study. "The existing evidence on the efficacy of cognitive behavioural and behavioural interventions on outwardly directed aggression in children and adults with learning disabilities is scant. There is a paucity of methodologically sound clinical trials. Given the impact of such behaviours on the affected individual, his or her carers and on service providers, effective interventions are essential. It is also important to investigate cost efficacy of treatment models against existing treatments. We recommend that randomised controlled trials of sufficient power are carried out using primary outcomes of reduction in outward directed aggression, improvement in quality of life and cost efficacy as measured by standardised scales."

3 Trial objectives

3.1 Primary objectives

The main objective is to evaluate the effectiveness, compared to normal care, of a manualized anger management intervention, delivered to people with mild to moderate learning disabilities in a service setting, in reducing levels of reported anger.

3.2 Secondary objectives

Secondary objectives, which address both outcome and process issues, are to explore and evaluate:

1) the effectiveness of the intervention in increasing anger coping skills and reducing levels of aggression;
2) the impact of the intervention on mental health and quality of life;
3) the extent to which similar results are observed by carers in the home setting as in day services;
4) the extent to which intellectual or receptive language ability, initial mental health status, carers' attributions of challenging behaviour, and/or the climate within the group, influence the outcome of the anger management intervention;
5) the cost consequences of the programme in relation to the utilization of health and social care services;
6) the experience of service users who participate in the programme
7) staff attitudes to and routine experiences of managing anger within services;
8) staff experiences of acting in the role of 'therapist' and the perceived impact of the intervention on the wider service.

4 Trial design

The study is designed as a multi-centre phase 3 cluster randomized controlled trial of a manualized anger management group intervention versus a waiting-list control group. The main objective is to evaluate the effectiveness, compared to

normal care, of a manualized anger management intervention, delivered to people with mild to moderate learning disabilities in a service setting, in reducing levels of reported anger. 30 services providing day activities for people with mild to moderate learning disabilities will be recruited. A total of 180 service users with mild to moderate learning disabilities, who are identified as having problems with anger control, will be invited to take part in the study. Each service will recruit 4-9 service users.

5 Service Selection

30 services providing day activities for people with mild to moderate learning disabilities will be recruited, on the basis that they report significant anger control problems among some of their service users. Within the current mixed-economy of care such services may be run by statutory or independent sector providers. In order to recruit a sufficient number of centres within the time frame of the project, it will be implemented in three different regions, one in Wales, one in England and one in Scotland, with a combined population of 5-6 million. In each region, 5 services will be identified, in each of two cycles (10 services in total): in each cycle 2-3 services will be allocated to the control group and 2-3 to the intervention group. This will allow sufficient time for the research staff in each region to recruit, train, oversee and monitor both the control and intervention arms.

5.1 Inclusion criteria for services

Each service will have:

1. Reported anger control problems among at least four service users who meet individual inclusion criteria and want to participate;
2. Availability of at least two staff members willing to be trained as group leaders;
3. Written agreement to participate from the service manager.

5.2 Exclusion criteria for services

Services will be excluded if:

1. The service is already running an anger management programme similar to this one;
2. There are no suitable facilities for group work.

6 Participant selection

Potential participants are eligible for the trial if they meet all of the following inclusion criteria and none of the exclusion criteria. All queries about participant eligibility should be directed to the Trial Manager before randomisation.

6.1 Inclusion criteria

1. An adult attending a service for people with mild to moderate learning disabilities;
2. Identified by service staff as having problems in managing their anger;
3. Wishing to learn to improve their anger management;
4. Able to provide informed consent;
5. Able to complete the assessments.

No attempt will be made to screen participants according to the presumed reasons for their apparent difficulty in controlling their anger, but it is recognised that anger may be a symptom of abusive treatment and, therefore, we will determine whether there are grounds for initiating a POVA procedure. As stated below, this would be a ground for excluding the person from the trial.

6.2 Exclusion criteria

1. Attending the service for a reason other than a diagnosed learning disability;
2. Currently receiving psychological treatment for anger or aggression;

3. Urgently requiring referral to a Clinical Psychologist for individual treatment of anger or aggression;
4. Experiencing circumstances which indicate that a Protection of Vulnerable Adults (POVA) procedure should be initiated;
5. If for any other reason the supervising Clinical Psychologist makes a clinical judgement that participation in the group would be counter-indicated.

7 Recruitment Process

Procedures for service and participant recruitment are outlined in the following sections.

7.1 No of services and participants

A total of 30 services and 180 participants will be required. Recruitment will be completed over 2 recruitment periods.

7.2 Recruitment process – services / service staff

Services will be recruited by direct contact between service managers and members of the research team, on the basis that they are able to include a cohort of service users who are identified as having problems with anger control.

All services and staff will be consented prior to randomisation and the incentive of receiving training at the end of the study is provided to avoid differential levels of dropout/engagement between the two groups of teams. Following baseline assessments, services will be randomly allocated to either an intervention group or a control group. Prior to randomization, staff training sessions will be provisionally scheduled for both groups, so as to ensure that training of the lay therapists in the 2 intervention arms can be completed 2 weeks post randomisation. Staff will be told that their training may be deferred if their service is selected to be in the control group. Service users within the intervention arm will be informed of their first group session date as soon as possible post randomisation.

In each participating service, at least two (wherever possible, three) staff will be recruited to act as lay therapists. Staff will be nominated by their manager and selected on the basis of their motivation to take on this role and their openness to use a cognitive behavioural approach, without reference to formal qualifications.

7.3 Recruitment process – service users/carers

All eligible service users will be identified by their key worker as having an anger problem or will have stated that they want help with their anger problem. 4-9 service users will be identified in the service. Service users will be approached and recruited before the team knows which arm of the study it has been allocated to.

Potential participants will be offered the opportunity to participate in an anger management group by their key-workers. The group will be presented as a potentially helpful activity comparable to other activities offered by the centre.
Service users who indicate an interest in participating will be introduced to the research team by their key-workers.

Services are small enough for services users to be well known to the staff who work with them: identification of potential participants will be from the personal knowledge of staff members, not from service users' records.

Home carers will be identified by the service users key worker once the service user has agreed to take part in the study.

7.4 Informed consent

A contractual agreement will be negotiated with participating services. Consent will be sought from five types of participants: the service users themselves, their key-workers and home carers, the lay therapists, and service managers. Written consent will be taken from lay therapists, key-workers, home carers and service managers (collectively, 'carers'), using consent forms and procedures that comply with standard REC guidelines.

7.4.1 Service staff

In each participating service, at least two (wherever possible, three) staff will be recruited to act as lay therapists. The Clinical Psychologist will explain the study to, and will take consent from, the service manager, key workers and lay therapists.
The following Patient Information Sheet (PIS) and consent form will be given to the identified staff by the Clinical Psychologist

Service managers, key workers and lay therapists – main study

1. General Information sheet

2. Consent form

Service managers, key workers and lay therapists – interview study

1. General Information sheet

2. Consent form

7.4.2 Service users

For service users, a more accessible consent procedure will be used:

(i) The trial will be explained verbally in simple terms, using a standard script written in accessible language, and checking frequently for understanding. At least 2 days will be given to consider and ask questions of researchers or carers. As long delays could be counter-productive in this group, the delay will be kept to a minimum, while ensuring that service users who wish to consult others have had the opportunity to do so.

(ii) In addition to the general information sheet, service users will also be given a simplified information sheet, to take home and read in their own time and at their own speed. It is important, when working with people with intellectual disabilities, to restrict the amount of information presented, so as to avoid information overload; therefore, the information script contains less information than might be usual with more able participants.

(iii) The explanation will repeated in a second meeting.

(iv) Consent will be recorded by the service user checking and initialling a set of tick boxes and signing the consent form.

(v) In order to assure that the service user has been properly informed, the whole process will be witnessed and signed off by a staff member who is independent of the research team.

For service users selected for interview after the end of the intervention, a separate consent will be taken at the time, using the same procedures as above.

Below lists the Patient Information Sheets (PIS) and consent forms for the service user:

Service user (main study)

1. Simplified accessible information sheet termed "Information Summary"
2. General Information sheet
3. Consent form

Service user (interview study)

1. Simplified accessible information sheet
2. General Information sheet
3. Consent form

7.4.3 Home carers

Home carers will be consented, by the Clinical Psychologist, as soon as possible after their respective service users. They will be given the following papers:

1. General Information sheet – main study
2. General Information sheet – interview study
3. Consent form

8 Withdrawal & loss to follow-up

Service users/key workers/carers/lay therapists have the right to withdraw consent from participation in any aspect of Trial at any time. The service users' care will not be affected at any time by declining to participate or withdrawing from the trial. Data collected up to the point of withdrawal, and any data that

could still be collected (eg. Carer assessments) will where possible be used in the analysis unless a service user explicitly asks for data to be excluded.

9 Randomisation

Randomisation will be performed using the method of minimisation. Centres will be balanced on their service users' average baseline self-reported provocation index, the number of service users recruited and the average number of hours a week spent by the service user with at least one trainer outside of sessions. A random component, set at 20%, will be used alongside the minimisation procedure to increase the integrity of the minimisation process.

Centres will be recruited, and baseline data will have been collected on all participating service users (of a particular centre), before randomisation of that centre takes place.

Centres will be randomised using an automated service provided by SEWTU.

10 Trial Intervention

10.1 Trial arms

10.1.1 Intervention Group

Participants will receive a manualized CBT intervention (Willner & Tomlinson, 2007), consisting of 12 weekly psycho-educational group sessions supplemented by 'homework'. Before the start of the intervention, a Clinical Psychologist will provide the lay therapists 2-3 training sessions, covering the principles of anger management and use of the manual, followed by fortnightly supervision during the intervention. Additional training sessions could be provided, at the discretion of the trainer.

All group sessions begin with a warm-up exercise, are punctuated by a tea/coffee break, and end with a relaxation exercise. Topics addressed over sessions

include: the triggers that evoke anger; physiological and behavioural components of anger; behavioural and cognitive strategies to avoid the build-up of anger and for coping with anger-provoking situations; and acceptable ways of displaying anger (assertiveness). Presentation relies heavily on brainstorming (e.g. "What makes us angry?") and role-play. After the first session, about a third of each session, is devoted to discussion by facilitators and group members of one or two participants' experiences, focussing primarily on problem solving around ways in which situations might have been handled differently to produce a better outcome. In addition to simplifying the language used in sessions, we avoid wherever possible the use of written materials, in favour of pictorial representations. Towards the end of every session, participants are asked to undertake a homework assignment, which consists of working with a staff member to complete a functional analysis ('hassle log') of a situation in which they have been angered that week, which is described, analysed and evaluated. As with the session content, homework is also simplified, by using the same homework exercise in every session, and presenting the material pictorially, in the form of a workbook. The functional analysis involves describing the context, the anger-provoking event, the participant's response, the quality of the outcome, and a consideration of how the anger coping skills taught in the programme could have been used to better effect (Willner & Tomlinson, 2007). At the end of the intervention, reports are provided on each of the participants, and recommendations are made for further input by staff to maintain and increase treatment gains. A version of each report will also be produced in a format accessible to the service user.

It is important to emphasize that, while there are only two publications on this specific protocol (Willner et al., 2005, Willner & Tomlinson, 2007), it exemplifies a standard approach, based on the methods developed by Benson and colleagues (Benson 1992, 1994; Benson & Ivins, 1992; Benson et al., 1986), that is very widely used across the UK within psychological services for people with learning disabilities. For example, the present procedure has only minimal differences from those used in several of the other published phase 2 trials (e.g. Willner et al., 2002; Rose et al., 2000, 2005, 2008). In response to requests, the manual for this intervention has been disseminated to around 200 centres within the UK and elsewhere and is in clinical use at many of them.

10.1.2 Control Group:

Participants will be on a waiting-list (support as usual: SAU) control condition. (One of the subsidiary aims of the project is to use qualitative methods to find out what 'support as usual' means in this context.) Staff in the control services will receive no training or support from project staff during the intervention phase. However, at the end of the study, staff in the control services will receive the same training and supervision provided to staff in the intervention services, so that they can provide CBT to service users in the waiting-list groups.

11 Serious Adverse Events

11.1 Definitions

11.1.1 Serious adverse events

Any untoward and unexpected medical occurrence or effect that:

- Results in death
- Is life-threatening [refers to an event during which the participant was at risk of death at the time of the event; it does not refer to an event which might have caused death had it been more severe in nature]
- Requires hospitalisation, or prolongation of existing hospitalisation
- Results in persistent/significant disability or incapacity
- Is a congenital abnormality or birth defect

11.1.2 Related AE

The SAE resulted from administration of any of the research procedures. (Causal to the research process or intervention)

11.1.3 Unexpected AE

The event is unexpected.

11.2 Reporting responsibilities of the centre

All adverse events that occur during the anger management program will be reported through internal processes already defined by the service. An additional step within each service internal procedure which will be, where the adverse event meets one of the serious categories this should be notified to the Clinical Psychologist. The Clinical Psychologist should then complete an SAE form and fax it to the Trial Manager within 24 hours upon becoming aware of the event.

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11.3 Evaluating and Reporting

The Trial Manager and/or the Chief Investigator will assess the nature of the SAE, for seriousness, causality and expectedness. Following the initial report, follow up data may be requested by the Trial Manager. Where the SAE is both related and unexpected the Trial Manager will notify the main REC within 15 days of receiving notification of the SAE.

12 Trial outcomes

12.1 Measures/assessment instruments

(i) Participant Characteristics

Intellectual and receptive language abilities will be assessed using the Wechsler Abbreviated Scale of Intelligence (WASI) and the British Picture Vocabulary Scale, 3rd edition (BPVS), respectively, which are standardized tests that are very widely used. Adaptive behaviour will be assessed using the short form of the Adaptive Behavior Scale (Hatton et al. 2001), which is completed by the service-user's key-worker. This assessment will be conducted at baseline by the researcher recruiting participants to the trial.

(ii) Process Evaluation

Resource inputs to deliver the intervention will be tracked (i.e., staff time in training, running the groups and supervision, travel costs and any administrative overheads).

The lay therapists will be asked to record the extent to which each session followed the session outline in the manual, and this will be explored with them in supervision. In addition, the three clinical supervisors will each arrange for an Assistant Psychologist from a research team outside of their area, to observe together the training being undertaken in their region against a checklist of core requirements, in order to provide an independent assessment of the treatment fidelity of two sessions (one towards the beginning and one towards the end of the intervention) in each participating service.

(iii) Quantitative Outcome Evaluation

Quantitative measures will be administered before and after treatment and at 6-months after the end of treatment. All assessments will be administered by Assistant Psychologists in interviews with the respondents. The researchers undertaking these outcome assessments will not have any involvement in training and monitoring the therapists. Assessment sessions will last a maximum of an hour, with longer assessments split over more than one session.

a) Primary Outcome measure:

The main outcome measure will be the Provocation Index (PI) as completed by the service-user, at follow-up. The PI is a direct measure of felt response to defined situations that may provoke anger and has frequently been used with this service-user group for the current purpose (Novaco, 1994; Taylor & Novaco, 2005).

b) Secondary Outcome measures:

Assessment will also involve completion of the PI by a key-worker (see also Willner et al, 2005; Willner & Tomlinson, 2007). For this and other measures, in

the event that a service-user's key-worker is involved in the trial as a lay therapist, then the measure will be completed by another staff member.

Aggression will be assessed by key-worker report using the Irritability domain items of the Aberrant Behavior Checklist (ABC) (Aman et al., 1985) and the Modified Overt Aggression Scale (MOAS) (Oliver et al., 2007). Both assessments have been either designed or validated for use with people with learning disabilities. Both were used to assess behaviour in a recent RCT of pharmacological treatment of aggressive challenging behaviour in adults with a learning disability (Tyrer et al., 2008). Key-workers' attributions in respect of challenging behaviour will be measured by the Controllability Beliefs Scale (CBS) (Dagnan et al, 2004).

The Profile of Anger Coping Skills (PACS) (Willner et al, 2005; Willner & Tomlinson, 2007) will be completed by both service-user and key-worker to assess the development of alternative, more functional coping skills.

Mental health will be assessed by using the Glasgow Depression and Anxiety Scales, which are recently established measures of depression and anxiety among people with a learning disability (Cuthill et al., 2003; Mindham & Espie, 2003), and an adaptation of the Rosenberg Self-Esteem Scale for people with a learning disability (Dagnan & Sandhu, 1999). Self-reported quality of life will be assessed by using the Comprehensive Quality of Life Scale - Intellectual Disability (ComQoL-I5) (Cummins, 1997).

(Note: While it is predicted that successful acquisition of anger control skills will improve mental health and quality of life, these measures will also serve to detect adverse effects of treatment.)

So as to assess generalization across settings, the anger, aggression and coping skills measures (PI, ABC, MOAS, PACS) will also be completed with home carers.

The following table summarizes the quantitative assessments to be carried out (with both intervention and SAU groups) at baseline, post-test and 6-month follow-up

Assessment	**Respondent**		
	Service user	**Key-worker**	**Home carer**
Wechsler Abbreviated Scale of Intelligence (WASI)	x		
British Picture Vocabulary Scale (BPVS)	x		
Provocation Inventory (PI)	x	x	x
Profile of Anger Coping Skills (PACS)	x	x	x
Aberrant Behaviour Checklist (ABC)		x	x
Modified Overt Aggression Scale(MOAS)		x	x
Controllability Beliefs Scale (CBS)		x	
Glasgow Depression Scale (GDS)	x		
Glasgow Anxiety Scale (GAS)	x		
Rosenberg Self Esteem Scale	x		
ComQoL-I5	x		
Adaptive behaviour scale (ABS)			x

13 Data collection/timing of assessment

The intervention will commence approximately 2 weeks after the groups are randomized. During this period, training will be provided to the lay therapists in the intervention group, and both groups of service users will receive SAU. The duration of the intervention and contemporaneous SAU is 12 weeks. Post intervention measures will be taken immediately in both groups in parallel (i.e., 16 weeks from randomisation in the SAU and intervention groups). Participants in both groups will be followed up 6 months later. Assessment will be carried out by the assistant psychologist.

13.1 Data handling and record keeping

The clinical psychologist supervising the lay therapists and the assistant psychologist are responsible for data collection. All consent forms and data related to the study will be collected and stored in the individual site files at the

NHS base/university of the clinical psychologist. Data will be stored in a secure locked cabinet. Anonymised data will be transferred from the NHS sites to the trial manager and statistician for data cleaning and analysis.

14 Statistical considerations

14.1 Practical arrangements for allocating services to trial groups

Once a centre has been recruited and baseline data collected on all participating service users, randomisation of that centre will take place. Allocation will be based on the method of minimisation, and will minimise on the average baseline self-reported Provocation Index (PI), the number of service users a centre recruits and the average number of hours spent by service users with at least one trainer outside of sessions.

14.2 Sample size

4-9 participants (mean = 6) will be recruited in each of 30 services. Each of the 3 regional supervisors will be responsible for recruiting and managing interactions with 5 intervention and 5 control sites.

Published studies of anger management in people with learning disabilities typically report large effect sizes. As service staff might be less effective therapists than psychologists, we will aim to detect a medium sized effect (d=0.57). This estimate is a conservative 40% of the effect size (d=1.35) observed in an earlier controlled trial using the same endpoint (Willner et al, 2005).

To achieve significance at $p<0.05$ with 80% power will require two groups of n=72 (allowing for ICC = 0.11). As there is no basis for estimating an ICC in the present context, we have used a value just above the range of ICC values reported in a recent systematic review (Eldridge et al, 2004), which varied between 0.01 and 0.1. This allows for the level of clustering that we would expect to see between participants naturally. As this is a group-based intervention, the effect in the intervention arm may well be to increase the degree of clustering. The analysis of the study will allow for this, but the sample has only been inflated

to allow for the underlying level of clustering of service users within services rather than the component that relates to intervention effect.

To arrive at the target of 72 participants in each arm of the trial, a single group of 4-9 service users (average = 6) will be recruited in each of 30 participating centres. This total of 180 participants allows for 20% loss to follow-up, which is a conservative estimate: no drop-out was observed in two earlier studies conducted in day-service settings (Willner et al, 2005; Willner & Tomlinson, 2007).

15 Analysis

15.1 Main analysis

The primary analysis will be intention to treat and will compare the mean self-reported PI between the two groups using a two level linear regression model, with participants at level 1 and centres at level 2, with baseline levels of the PI as a covariate. Secondary outcomes will be analysed similarly. Variables will be transformed prior to analysis if necessary to fulfil assumptions of normality.

15.1.1 Sub-group & interim analysis

Formal subgroup analysis of those who are above a threshold of self-reported PI of 1.0 at baseline, and those who meet formal criteria for a diagnosis of 'learning disability', will be undertaken through the fitting of interaction terms to the primary model. Other exploratory analysis will assess whether or not the effect of the intervention differs in different service settings (statutory/independent) and by intellectual and language ability.

The associations between self and key worker/home carer reports will be assessed and compared between intervention and control groups. The association between anger coping skills and outcomes such as provocation, mental health and QoL will also be assessed.

A complier adjusted causal effect (CACE) will be estimated using a multi-level mixture analysis (Jo et al., 2008) to assess the impact of non-compliance with the intervention on the effect shown. A complier will be taken as someone who has attended at least two thirds of the sessions (8 of 12). None of the control group will be able to access the intervention.

15.2 Qualitative Evaluation

a) Service users

A sample of service users will be interviewed after the intervention to gain an understanding of their experiences of participating in CBT. This part of the research is not hypothesis driven but aims to gain an 'insider's perspective' from which a theoretical framework regarding the subjective experiences of service users can be developed.

The chosen analysis for this data is Interpretative Phenomenological Analysis (IPA). IPA attempts to reduce the complexity of experiential data through vigorous and systematic analysis in a transparent and plausible manner (Smith, 1996). It has a specific psychological focus and is suitable for data collected from less articulate/forthcoming participants. A small number of participants are required: service users will be randomly selected from a "short list" of those participants who are considered to have sufficient expressive language ability to be interviewed.

b) Therapists

The therapist who has been most active in terms of running each group (N=15) will be interviewed post-intervention in order to investigate their experiences of learning and applying new therapeutic skills as cognitive behavioural therapists, and their impressions of the 'climate' within the group and the impact of the group on the wider service. The focus of this evaluation is on the therapists' personal, subjective experiences and therefore IPA will again be utilised as the most appropriate qualitative analysis.

Both service user and therapist interviews will be conducted according to a semi-structured interview schedule, containing questions which encourage the

participants to focus on 'personal meaning' and making sense of their experiences of the therapeutic process.

c) Managers

A related, but separate, part of the qualitative evaluation aims to gain an understanding of service policies and practices for service users who express anger inappropriately. This will be accomplished by interviewing all service managers, in both intervention and support-as-usual services (N=30), before the intervention and at follow-up. As the topic in question demands a structured, factual line of enquiry, Thematic Analysis (TA, Aronson, 1994) will be used to categorise participants' responses into themes and sub-themes. Responses will be grouped according to each of the questions posed during the structured interview and will be analysed as such, in order to establish common themes and differences within and between services before and after the intervention. A particular focus of this part of the evaluation will be the perceived influence that the CBT trials have had on the clinical practice within each of the services.

Both of the qualitative evaluations (IPA and TA) will be subjected to 'triangulation' which involves presenting relevant participants with a summary account of the findings in order to establish whether the analyses have produced an account which is credible and comprehensible to its informants.

d) Relationship between qualitative and quantitative evaluation

We anticipate that the qualitative data will enhance the quantitative analyses in four distinct ways.

Firstly, as with any well-designed mixed-methods study, we will aim to generate a productive interaction between the quantitative and qualitative analyses: exploratory quantitative analysis will be undertaken to explore possible inter-relationships between factors identified in the qualitative analysis; similarly the qualitative data will be reviewed to explore evidence in relation to findings that emerge from the quantitative modelling.

Secondly, while the quantitative data will provide answers to the question of the effectiveness of the intervention, they will not provide insights into the process or mechanisms of change. This information will, however, emerge from an account of the participants' (both service users and staff) experience of the groups and their understanding of the intervention. The qualitative findings will also influence the interpretation of the outcome data by indicating the personal salience (as distinct from the statistically significance), for clients or those affected by their behaviour, of any changes that are found. And if there are negative results, the qualitative data, alongside the assessment of the fidelity of intervention delivery, may help to explain them.

Thirdly, interviewing participants and staff may identify unanticipated outcomes of the group, either positive or negative, and barriers to change. (For example, in the study of anger management by adolescents cited earlier, qualitative analysis identified some clinically important but unanticipated moderating effects of participants' ages on outcomes, which were confirmed in a reanalysis of the quantitative data.)

Finally, if the study shows positive results, the qualitative data, including the impact of the intervention on the culture within day services, will inform the roll-out of the intervention to the wider community.

15.3 Service Utilisation Costs and Consequences evaluation

The economic analysis will be in the form of a cost and consequences analysis. We rejected a cost utility approach because we believe that the utility-based health state measures such as EQ-5D required for such analyses would not be sensitive to the effects anticipated from the intervention. We rejected a cost effectiveness approach partly because of the multiple objectives of the intervention (e.g. aggression, controllable beliefs, coping, self esteem), which cost effectiveness analysis cannot handle, and partly because the primary outcome measure, the provocation index (PI), is not an effect that features in economic analyses of related interventions. Unless our intervention is shown to be dominant (more effective and less costly than usual care) then an incremental cost effectiveness ratio in terms of extra cost per unit PI would be of little value in informing policy. The proposed cost and consequences analysis is, strictly, not a technique of economic evaluation as it cannot provide a definitive answer to questions of either allocative or technical efficiency. It does however identify the

direct and indirect costs (and/or savings) of the intervention and considers these in relation to the range of observed effects.

The costing will be undertaken as follows;

1) All resources used in delivering the intervention will be recorded prospectively and valued using standard methods (Drummond et al, 2005) with unit costs provided by the study sites. Resource inputs would include:

(i) Time input of (a) the applicants to train/supervise the clinical psychologists implementing and supervising the intervention, (b) the clinical psychologists in training and supervising the day service lay therapists running the groups, (c) the day service lay therapists in running the groups, (d) administrative/secretarial staff attributable to the intervention.

(ii) Travel costs attributable to the intervention.

(iii) Consumable costs attributable to the intervention (e.g. production of manuals).

2) All other resources used by study participants at the intervention sites, and all resources used by study participants at control sites will be monitored prospectively using various recording logs overseen by the research assistants. These will be valued using standard methods with unit costs provided by the study sites.

3) All relevant resource use, apart from those at the study sites, will be collected at baseline and at follow-up using the Client Service Receipt Inventory (CSRI). CSRI is a validated tool to measure total package resource use and has been used in evaluations involving service users with psychiatric problems and service users with learning disabilities It records items such as contacts with community-based primary care, other health or social services, educational services, outpatient and inpatient attendances, etc. Unit costs for most of these are available from Curtis (2008).

The study will be run under the aegis of the South East Wales Trials Unit (SEWTU) and will therefore have access to all SEWTU resources including health

economists. Prof. David Cohen, University of Glamorgan, is responsible for the health economics elements of SEWTU and will oversee the economic analysis in this trial to ensure that it conforms to established costing methods.

Additionally, Prof. Martin Knapp, who has a long-standing working relationship with Prof. David Felce, has agreed to act in an advisory capacity for this trial. Prof. Knapp is Professor of Social Policy and Director of the Personal Social Services Research Unit at the London School of Economics and also Director of the Centre for the Economics of Mental Health at King's College London, Institute of Psychiatry. He has extensive expertise in the economics of mental health and was responsible for development of the CSRI being used in this trial.

15.4 Data storage & retention

All data will be kept for 15 years in line with Cardiff University's Research Governance Framework Regulations for clinical research. Electronic data will be stored on fire-walled University and NHS computers. Files will be password protected and only accessible to researchers responsible for the running of the study and the Chief Investigator. All procedures for data storage, processing and management will be in compliance with the Data Protection Act 1998. All participants will be given a unique study number and no personal details will be retained. All paper records will be stored in a locked filing cabinet, with keys available only to researchers and the chief investigator. The Trial Statistician will carry out analysis. All essential documents generated by the trial will be kept in the Trial Master File.

16 Trial closure

The end of the trial will be considered as the date on which the last participant has completed their follow-up assessment

17 Regulatory issues

17.1 Ethical approval

The Chief Investigator has obtained ethical approval from the South East Wales Ethics Committee (REC). The principal investigators in each of the three regions will seek R & D approval from their home Trusts before any recruitment begins.

Approval in principle to undertake the research will be obtained from an umbrella social services body, depending on what exists in each region (e.g., in Wales the 22 local authorities have a Learning Disability Policy Committee, which will consider the application soon after it has been submitted).

Risks and anticipated benefits for trial participants and society

There are no significant risks to participants or society. There is a hypothetical risk that a client's condition could be worsened by participation in the group, but the likelihood of this happening is extremely small: there were no clients in any of our earlier published trials for whom we would attribute participation in the group as the reason for a clinical deterioration.

The potential benefit to participants is that participants will learn to express their anger more appropriately, with a concomitant decrease in aggression, so increasing their opportunities for social inclusion, and decreasing the risk of placement breakdown, exclusion from services, and involvement with the criminal justice system. The potential benefit to society is the avoidance of these outcomes, which are costly to services and impinge on other service users and members of the public. There are also potential benefits to participating services, in relation to job enhancement and increased self confidence for the staff who act as therapists, and a less challenging working environment and improved organizational culture for all staff.

17.2 Confidentiality

The Chief Investigator and the research team will preserve the confidentiality of participants in accordance with the Data Protection Act 1998.

17.3 Indemnity

Cardiff University will provide indemnity and compensation in the event of a claim by, or on behalf of participants, for negligent harm as a result of the study design and/or in respect of the protocol authors/research team. Cardiff University does not provide compensation for non-negligent harm.

17.4 Trial sponsorship

Cardiff University will act as sponsor for trial.

17.5 Funding

This study is funded by the Health Technology Assessment Programme (HTA).

17.6 Audits & inspections

The trial is subject to inspection by NCCHTA as the funding organisation. The study may also be subject to inspection and audit by Cardiff University under their remit as sponsor.

18 Trial Management

The TMG will consist of the Chief Investigator, Co-applicants, Research Staff, Service User, Trial Manager, Trial Statistician and Trial Secretary. The role of the TMG is to help set up the study by providing specialist advice, input to and comments on the Study procedures and documents (information sheets, protocol etc). They will also advise on the promotion and the running of the trial and deal with any issues that arise. The group will meet, either face to face or using audio-conferencing facilities, monthly throughout the course of the study.

19 Data monitoring & quality assurance

19.1 TSC (Trial Steering Committee)

A TSC will be established and will meet annually, consisting of an independent chair, and six other independent members. All appropriate disciplines have been covered in choosing the TSC members. The TSC will consist of a chair, a Consultant Clinical Psychologist, a statistician, a service key worker and two service users. The Trial Steering Committee (TSC) will provide overall supervision for the trial and provide advice through its independent chair. The ultimate decision for the continuation of the trial lies with the TSC. The nature of this study makes it unlikely that an Data Monitoring and Ethics Committee *(*DMEC) will be required; however, this will be discussed with the TSC at their first meeting and a DMEC will be set up if deemed necessary

19.2 Data Monitoring Committee (DMC)

The TSC will initially fulfil the role of a Data Monitoring Committee (DMC), unless they decide to constitute a separate DMC.

20 Publication policy

All publications and presentations relating to the study will be authorised by the Trial Management Group.

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22 Appendices

N/A