NIHR HTA Programme

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PRODIGY: Prevention of long term social disability amongst young people with emerging psychological difficulties: a pilot randomised controlled trial of social recovery cognitive behavioural therapy.

1. Research Objectives

The aim is to undertake a pilot randomised controlled trial involving 50 treatment and 50 control cases to constitute the internal feasibility phase of a substantive trial. The objectives are:

a) To assess recruitment rate, quality of data collection and follow up.
b) To provide a final check on procedures in the protocol.
c) To conduct a qualitative sub-study to inform the objectives, using a qualitative, service user perspective.

At 12 months the trial steering committee will check criteria for progression to a full trial including the data collected in this study as a feasibility phase. The criteria will be:

a) No necessity for substantive changes to protocol
b) Recruitment within 80% of planned in the first 12 months.
c) Retention of participants within the study with baseline and outcome assessments completed over 80% for the secondary outcomes and mediators and 90% for the primary outcome.
d) Satisfactory delivery of competent and adherent therapy to more than 80% of the treatment group.

If these criteria are met we will continue to recruit and seek approval to extend the study and involve another centre to complete a substantive definitive trial. If these criteria are not met we will continue to collect data up to a total of 100 cases and analyse and report the study as an external pilot.

2. Existing Research

It is now widely recognised that most socially disabling chronic and severe mental health problems begin in adolescence with 75% of all severe and chronic mental illnesses emerging between 15 and 25 (Kessler, et al., 2005; Kim-Cohen, et al., 2003). A series of retrospective studies have consistently shown that severe mental illness is often preceded by social decline, that this often becomes stable, and that such pre-morbid social disability is predictive of the long term course of the disorder (see Fowler, et al., 2010 for review). Between 3% and 5% of adolescents present with complex mental health problems associated with social disability (Kim-Cohen, et al., 2003). The young people at highest risk of long term social disability present with emerging signs of social decline, in association with low level psychotic symptoms, emotional and behavioural disorder (often accompanied by substance misuse problems and risk to self and others) (Kim-Cohen et al., 2003, Kessler et al, 2005). Despite poor outcomes and cost of disorders leading to social decline, young people with complex needs frequently do not access treatment and fewer than 25% of young people and their families who have needs get access to specialist mental health services (DoH, 2008; Singh et al, 2010). More complex cases are found in areas of social disadvantage, and in youth justice, local authority care and learning disability services. The economic costs of not addressing this disability are very large (Mangalore, & Knapp 2007).

Several recent reports have highlighted that there is a major gap in identifying and managing the mental health problems of young people with severe and complex mental health problems and particularly those at risk of social disability (DoH, 2008; Singh et al, 2010). New approaches to detection and intervention are required to meet the needs of these young people. There is a gap in the evidence base for these types of cases. These young people have severe and complex mental health problems and thus they tend not to be suitable or respond to short term evidence based therapies for more discrete mental health problems, such as CBT for anxiety, depression and conduct disorder which are available in IAPT. Also while this group show clear evidence of social disability they do not meet criteria for first episode psychosis and so they are not suitable for first episode psychosis services for which there is now considerable evidence of benefits on social functioning (Addington et al, 2005; Bertelsen, et al., 2008; NICE guidelines schizophrenia, 2009). Our aim in the present project is to identify and target this group and offer a new psychological intervention specifically tailored to their needs.

Current evidence for effective interventions to address social disability amongst young people in the early course of severe mental illness is very limited (see Fowler, et al., 2010 review). A series of studies have been undertaken which have aimed to identify cases at Ultra high risk of poor long term outcome associated with severe mental illness (Addington, et al., 2007; Klosterkotter, et al., 2005; McGorry, et al., 2002; Morrison, et al., 2004; Morrison, et al., 2011; Yung, Phillips, Yuen, & McGorry, 2004; Yung, Stanford, et al., 2006). The

success of the Ultra high risk studies is that it has been shown that it is possible to set up services to identify and treat cohorts of young people who can be identified as having "At Risk Mental States" (ARMS) using defined operational criteria and structured assessment tools (Yung, Phillips, et al., 2006). Furthermore, these studies have consistently identified that those who are at the highest risk are young people who present with social decline as well as sub-threshold psychotic symptoms (Yung, et al., 2010; Lin et al, 2011).However, the focus of these studies has been on prevention of episodes, or symptoms of psychosis, not social disability (Yung, et al., 2010).Recent studies have shown that cohorts identified using these criteria may have more transient problems than previously thought and only a subset go on to have long term social disabling mental health problems (Yung, et al., 2010; Lin et al, 2011). Several prominent Ultra High Risk researchers are now highlighting an alternative strategy which is to examine functional outcome in the ultra high risk group. This study is consistent with this strategy.

Systematic reviews of CBT for psychosis including nice guidelines have consistently shown moderate effect size on improvements in social disability where this has been assessed as a secondary outcome (Wykes et al, 2008; NICE guidelines for Schizophrenia, 2009), however these studies have predominantly been carried out amongst chronic participants not young people. The feasibility of using CBT with young people who are at ultra high risk of long term poor outcome has been shown the recently completed EDIE 2 mulitcentre study (Morrison, et al., 2011) which has shown reductions in severity of psychotic symptoms. However, the focus of the therapy in EDIE 2 was symptom reduction (French & Morrison, 2004) and this approach neither targeted nor had a significant benefit on social disability. EDIE 2 clearly demonstrated the ability of collaborating sites to recruit young people at high risk and successfully retain them in research and therapy. However, as described above the group recruited in EDIE2 were heterogeneous in terms of social disability. The present trial moves on from EDIE by focussing on a group which have a more homogeneous set of social disability problems defined by low activity levels and targeting this group with a multisystemic intervention which specifically aims to address social disability.

Better outcomes on social disability and hopelessness can be obtained from a more targeted intervention specifically focussed on improving social disability amongst those who have low functioning. We have developed a multisystemic form of CBT which targets social disability and have published a successful MRC trial platform study carried out amongst a group of young people who had established chronic and severe social disability problems some years after first episode psychosis. This trial demonstrated gains in structured activity and hope as well as reductions in symptoms (Fowler, et al., 2009). Clear indications of health economic benefits were also demonstrated (Barton, et al., 2009) although the trial was small and there was a large level of uncertainty associated with these estimates. We have subsequently applied this type of approach in clinical practice widening our selection criteria to include all young people presenting with severe and complex mental health problems at risk of social disability, drawing from our experience with EDIE 2 and this has been highlighted as an example of good practice (Joint Working at the Interface, 2011). We are now ready to undertake the feasibility phase of a substantive trial, which will be the first to specifically aims to address functional disability problems amongst the high risk population.

3. Research Methods

Design: The study will be a single blind, randomised controlled trial comprising of a 9 month intervention and 6 month follow up period involving 50 treatment cases and 50 controls in two centres. The study will constitute the feasibility phase undertaken in preparation for a large multicentre trial. A qualitative sub-study will be embedded within the pilot trial to evaluate the intervention from the subjective perspectives of patients themselves. Depending on data quality and recruitment the data will either be used as an external pilot or as the internal feasibility phase of a substantive trial. The NIHR accredited Norfolk Clinical Trials Unit advised on the development of the protocol and will provide ongoing expertise during the conduct of the study.

Setting: The intervention will be conducted in secondary mental health care settings, by therapists based in outpatient youth mental health early detection and early intervention services in mental health trusts in East Anglia (Norfolk and Suffolk) and Manchester.

Target population: Young people aged between 16-25 presenting with persisting signs of social disability operationally defined as engaged in less than 30 hours structured activity per week and who are presenting to youth services in East Anglia and Manchester. They will also be presenting with either a). Attenuated symptoms of psychosis which meet criteria for an at risk mental state, or b). less severe attenuated psychotic symptoms and the presence of severe and complex mental health problems operationally defined by a score of less than 50 on the Global Assessment of Functioning (GAF) score. All potential referrals will be screened first with GAF

score, then activity levels will be checked by the Time Use Survey and symptoms assessed by the Comprehensive Assessment of At Risk Mental States (CAARMS).

Project timetable: The study will take place over 2.5 years (30 months). This involves a 15 month recruitment period in which we can realistically expect a rate of 3-4 participants randomised per month in each site. Given this rate of recruitment, we can expect to recruit to target to meet the 50 participants required from each site. Each participant will have a 9 month intervention and six month follow up. Recruitment will be monitored continuously via an independent DMEC.

Feasibility of recruitment: We confidently anticipate that we can achieve the recruitment targets by sampling across early detection and youth services in East Anglia and Manchester. Both research sites are nationally recognised centres of clinical excellence which have successfully collaborated and led a series of related studies. The staff and managers involved in both sites are highly motivated to participate and are familiar with recruiting participants into research trials. Both sites have extensive existing links with agencies in primary care, child and adolescent, and adult mental health services, with established referral pathways for recruiting these types of cases into both clinical services and research. Both sites have existing services which already receive referrals of cases with At Risk Mental States at a rate of around 80 per year (total 160 per year in both centres). EDIE 2 data suggests that approximately, 60% of these existing referrals are likely to meet criteria for the present project. Referrals who meet inclusion criteria for existing At Risk Mental State Services will therefore provide approximately 90 suitable cases per year from which to recruit from. In addition, as described above, we will be widening recruitment criteria to include cases who are presenting with early signs of social disability and severe and complex mental health problems but who have less severe attenuated psychotic symptoms (and are thus at present excluded from psychosis and At Risk Mental State Services). Our estimates are that this is likely to at least double the population at risk. Referrals of this type are already received by our existing services (though presently excluded) and further referrals can easily be stimulated via screening and liaison with the close links both services already have with IAPT, counselling and youth offending services. In Norfolk services are being re-oriented to facilitate engagement of young people with severe and complex problems into secondary mental health care. This should facilitate the present study. If recruitment falls 20% below planned rates at key time points we will not proceed to full trial.

Allocation to groups: Following pre trial assessments consenting participants will be randomised to study arms stratified by age (16-19, 20-25); severity of social disability (Not in Education, Employment and Training or not) and meeting symptomatic criteria for an At Risk Mental State or not. Both groups will receive standard treatments as applicable. A remote, randomisation service will assign allocation to groups coordinated by the Norfolk Clinical Trials Unit.

Blinding: We will not be able to blind participants to treatment group. We will blind outcome assessors to group. To do so, following allocation to the treatment or control arm, all participants in the study, their care coordinator and the service user's clinical team will be asked not to reveal the group to which the participants were randomised to their assessor. Interview participants will also be asked at the beginning of each assessment interview not to disclose the group to which the individual was allocated. Outside the assessments, outcome assessors will be shielded from discussion of participants in study forums where the possibility of determining the allocation group of the participants could be determined. Qualitative interviews will be carried out by a researcher from another service or a university researcher independent of the clinical team. With the assistance of the Norfolk CTU we will use a system of web based data entry to ensure that assessors will not have access to information in the data base that would reveal the allocation group. To test the success of blinding we will ask the assessor to guess the allocation group for each participant at the end of each assessment.

Training of trial raters: The trial research assistants will be trained in the use of all measures by members of the team. Joint ratings with one another and with members of the team supervising them will be used to establish reliability.

4. Planned interventions

Experimental: Multisystemic Social Recovery Cognitive Behavioural Therapy (MSRCBT). The intervention used will be an adaptation of the intervention used in our previous studies and described in our therapy manual (Fowler et al, In Press). The therapy is based on a cognitive behavioural model which suggests that social disability evolves as a result of life style patterns of low activity, which are adopted as functional behavioural patterns of avoidance and maintained by lack of hope, sense of agency and low motivation. The intervention involves promoting a sense of agency, hope and motivation and encouraging activity while managing psychotic symptoms and associated problems such as emotional dysfunction and cognitive neuropsychological deficits.

Preliminary tests of mediation hypotheses provide support for the model (Hodgekins and Fowler, 2010). The focus is pragmatic and combines multisystemic working with use of specific CBT techniques. Therapists adopt assertive outreach youth work principles and also draw from successful social and vocational interventions such as supported education and employment interventions. The intervention specifically focuses on engaging young people with severe and complex mental health problems into treatment and addresses the presence of multiple co-morbidities and potential cognitive difficulties.

The intervention involves three stages: Stage 1 involves assessment and developing a formulation of the person in social recovery. This often involves validation and acceptance of real barriers, threats and difficulties, while focusing on promoting hope for social recovery. Stage 2involves identifying and working towards medium to long term goals guided by a systemic formulation of barriers to recovery. A particularly important aspect of this is identifying specific pathways to meaningful new activities. Where relevant this includes referral to relevant vocational agencies, or alternatively direct liaison with employers or education providers. Cognitive work at this stage involves promoting a sense of agency, consolidating a positive identity and addressing feelings of stigma and negative beliefs about self and others. Stage 3 involves the active promotion of social activity, work, education and leisure linked to meaningful goals, while managing symptoms. This involves specific cognitive behavioural work managing symptoms using behavioural experiments. Treatment fidelity will be assessed by taped treatment sessions and therapy notes using specific assessments of adherence and competence. The procedures are defined in a published treatment manual (Fowler et al In Press) which includes specific case examples. Considerable clinical material and presentation material including video is available for training purposes. The intervention is delivered over 15 sessions over a 9 month therapy window. It is designed for use in secondary early detection and intervention mental health services and differs substantially from currently available short term CBT available in adult mental health, Improving Access to Psychological Therapies (IAPT) and CAMHS services. Therapists will offer a combination of clinic based appointments but also outreach work and home visits to maximise engagement and the application of learning to real life settings. This is a standard approach to delivering CBT with this type of client group. We have already demonstrated the feasibility of delivering this type of approach to young people with severe mental illness in prior feasibility studies and in past trials with similar types of participant groups (e.g. EDIE 2 MRC trial).

Control: Our methodological approach is to compare "current standard outpatient NHS treatment" with our new form of outpatient care "standard NHS treatment plus multisystemic cognitive behaviour therapy". Current existing NHS standard outpatient treatment for young people with non-psychotic severe and complex problems and social disability involves the provision of short term individual and family psychological therapies within the Improving Access to Psychological Therapies (IAPT) and Child and Adolescent Mental Health Services and medication management, support and monitoring. Participants may also receive a range of education, training, vocational and youth work interventions from a variety of statutory and non statutory service providers (including social services, employment and education providers). The aim of the study is to test whether the addition of the provision of multisystemic cognitive behaviour therapy for young people with severe and complex mental health problems and early signs of social disability by secondary mental health care NHS services assists the promotion of social recovery above and beyond that provided by existing interventions available in routine services in the UK. Our intention is to carefully monitor the service contacts received across a range of services in both arms of the trial using a specifically adapted version of Client Service Receipt Inventory (Thornicroft et al, 2006). We will follow procedures adopted in other trials and provide all referrers with a best practice manual for standard treatment which summarises good practice including referral to IAPT services and medication management where appropriate. Participants will not be denied any existing service in either therapy or control arm of the trial. In both arms of the trial they will be encouraged to engage in and continue with existing treatments. In the therapy arm the multisystemic cognitive behaviour therapists are trained to liaise and coordinate their work with other agencies.

We will not be asking referrers to withhold any treatment. We will provide referrers with a best practice manual which gives guidance on providing optimal standard treatment for this type of case. Treatment as usual for this population should involve provision of short term individual and family psychological therapies available in IAPT and Child and Adolescent Mental health services and medication according to disorder specific protocols. Standard psychiatric care, psychological and vocational interventions from a variety of agencies will also be available to both treatment and control arms. All service contacts will be monitored during the trial duration. In addition our assessments will identify any risks to self or others and this will be communicated to the referring clinicians.

Anticipated problems with compliance: We are aware that young people with severe and complex mental health problems who are socially withdrawn with low activity levels often present challenges to clinical services, not least, that they may disengage from treatment. Despite this, our clinical experience with this type of

patient group is good. In our trial platform we achieved follow up data from over 90% of eligible clients on constructive economic activity (work, education) assessed by telephone and over 80 % from face to face interview assessments and we are confident in achieving similar levels of outcome with this participant group. Importantly the primary outcome assessment is Time Use and a useful estimate of time in constructive economic activity (work, education, voluntary work) can be assessed by telephone contact and triangulated by case worker report. All who enter the trial will have given permission to be contacted in this way. Similarly both our intervention and our assessment procedures are designed to be flexible and work in an outreach way to deliver the intervention and conduct assessments wherever is suitable for the participant. We have developed extensive experience over many years in managing such procedures in ways which are welcomed by young people with severe and complex mental health problems, safe for assessors and therapists and result in good levels of outcome.

Training and delivery

Selection and training of clinicians: At the present state of the development of the intervention this is best delivered by therapists who have had training in CBT skills either as part of a post-qualification training course in CBT or as part of clinical psychology training programme. In the MRC trial platform we used both trained therapists and untrained case managers and found that only those who had had specific training had the confidence to effectively deliver some of the more specific behavioural experiment techniques which were associated with improving activity. All therapists recruited to work on the trial will have experience in working with this type of case, and will receive a series of pre trial workshops and ongoing training and supervision from expert therapists (DF and PF).

Assessment of content of treatment: Therapists will be asked to tape sessions with clients and to record the use of specific treatment techniques in notes and recording sheets. The tapes will be rated using the Cognitive Therapy Rating Scale (CTRS) and a specific adherence tool suitable for the manual. We have extensive experience in this area (Fowler, Rollinson, & French, 2011) and DF and PF are regularly asked to advise and consult on other trials. We will draw from procedures we used effectively in EDIE 2.

5. Planned inclusion/exclusion criteria

Inclusion criteria

Young people aged 16 to 25 with severe and complex mental health problems showing early signs of persistent social disability presenting to secondary mental health care services.

Presence of impairment in social and occupational function indicated by reduced patterns of structured and constructive economic activity of less than 30 hours per week and a history of social impairment problems lasting for a period of longer than 6 months.

Presence of severe and complex mental health problems defined operationally as a) having attenuated psychotic symptoms which meet criteria for an At risk Mental State, or b) having less severe attenuated psychotic symptoms but having severe and complex mental health problems which score at least 50 on the Global Assessment of Function Scale (which indicates the presence of severe symptoms of at least two of depression, anxiety, substance misuse of behavioural or thinking problems or subthreshold psychosis to the degree to impair function). Also having a history of at least moderate symptoms persisting for longer than 6 months.

Exclusion criteria

Age below 16 or above 25 with active positive psychotic symptoms or history of first episode psychosis.

Severe learning disability problems (though mild to moderate learning difficulties will not be excluded).

Organic problems.

Non English speaking to the degree they are unable to fully understand and answer assessment questions or give informed consent.

6. Ethical arrangements

Risks and anticipated benefits for trial participants and society including how benefits justify risks

The benefits of early detection of severe mental illness and prevention of long term disability are yet to be demonstrated hence the need for this trial. However, it seems sensible to try to offer accessible and prompt help to distressed people who are seeking it. The intervention we are suggesting has good face validity as an intervention, since it is likely to be acceptable - for some time, service users have encouraged clinicians to focus on recovery as being more than an absence of symptoms and the assertive outreach approach is likely to be beneficial for individuals with poor functioning who may struggle to access established psychological services.

It is clearly possible that stigmatisation, fear of developing serious mental illness and self-imposed restrictions on activity (for fear of provoking illness) may be unintended consequences of delivering the intervention. However, the collaborative, problem-orientated structure of the intervention means that it is likely to be able to identify and target any adverse developments within the therapy process itself (for example, by helping patients set realistic and achievable goals in many different areas of life). Whilst there are some risks of recruiting young participants into a research study, especially those below the age of 18, it is important to acknowledge that participants must be help seeking. In addition the nature of the intervention which is collaborative and problem orientated will minimise concerns. As the earlier section outlining ethical considerations noted, considerable care will be taken to the processes of sharing information about the study, the gaining of consent, the research processes for gathering information from young people and arrangements for supporting them throughout their involvement in the study. All participants will be provided with a 'Crisis Card' listing the contact details of organisations that provide help and support to people experiencing mental health difficulties, as well as contact details for their Trial Therapist if applicable. The cards will also advise participants to visit their GP or Accident and Emergency in the event of a mental health crisis. Our methods draw on well-established good practice in this area (e.g. national studies undertaken by YoungMinds, the Mental Health Foundation and others) and also draw on the views and suggestions of young people themselves, including those we consulted in developing our methodology.

Within this trial, a protocol for monitoring adverse events will be employed (and monitored by the DMEC). The trial will also employ measures of potential side effects (stigmatisation and distress), which have been identified as potential adverse consequences in ethical debates within the literature and at a Wellcome Trust-funded Ethics Workshop held at the University of Manchester in 2003. As regards the issue of denying a willing and eligible person the intervention the evidence in support of the intervention is at present uncertain, accordingly it cannot be said that allocation to TAU is being denied an effective intervention. Indeed both arms will receive an enhanced intervention above and beyond what is offered in the health service as they will receive extra assessments and contact with the research team which qualitative research has often revealed to be perceived as helpful. With regards to maintaining confidentiality, we will take all standard precautions to negate this risk. Documents from completed assessments containing sensitive personal information will be identified only by code and filed away in locked cabinets in locked rooms separate from information identifying individuals to ensure absolute confidentiality. Encrypted computer software will be used whenever electronic data transfer is required. There will be close liaison with all staff and mental health teams working with the young people recruited to the study. It is good practice to ensure such close relationships between treatment teams and research teams in working with young people with severe and complex mental health teams and we will ensure our written and verbal information makes it clear that all participants are informed at time of consent that information will be passed to the treatment team to inform clinical decision making as necessary.

Arrangements for participants still at school: 1. We would ensure that all appointments/interventions are offered at times that as much as possible do not clash with important school commitments (e.g. timed to be after school). 2. With young people's consent, we would inform their school of their involvement in the study and would liaise as required with relevant school pastoral and health care staff, e.g. the school nurse, counsellor, SENCO, to facilitate a joined up and coherent package of support to the young person; parents/carers would also be involved as appropriate. We would also ask school staff to maintain contact with us re: any untoward effects on school attendance/performance etc. as a result of a young person's involvement in the study. 3. Information will be age-appropriate for those still at school. Regarding assessment it should be noted that the time use assessment assesses activity i.e. school or education attendance not simply registration. The aim for participants at school would often be to improve school or education attendance.

Informing potential trial participants of possible benefits and known risks and obtaining informed consent: The participant and professionals information sheets include information about possible benefits and risks. Staff familiar to the young person, or their care coordinator, will be involved in informing young people

about the study, in collaboration with a research assistant who will have been carefully trained by the applicants in procedures for eliciting informed consent from young people with mental health problems. Young people will be supported as required throughout their involvement in the study (e.g. post assessment or interview). Time for them to consider their participation in the study will be factored in and we will not include individuals who do not have capacity to consent to participation or who are currently detained in hospital.

Proposed time period for retention of relevant trial documentation: All hard copies of the trial data will be kept in a locked room in a locked cabinet at UEA in the Norwich Medical School or at participating NHS sites for the period of the trial and for a balance of ten years. All of this information will be coded and kept separate from the identifying information. Thereafter, it will be destroyed using the confidential shredding and recycling facility made available for the disposal of all confidential written material at the university or participating NHS sites.

7. Proposed sample size: Our intention for the pilot study is therefore to recruit 100 participants, 50 treated cases and 50 controls. This will allow the assessment of recruitment and feasibility of intervention across this age range together with an assessment of variability in outcome for a future power calculation. The qualitative study will be carried out with 16 participants (8 from each group) who will be selected using a sampling frame, drawn to sample purposefully for key constituencies, such as age, presentation, symptoms and previous history.

If it is decided to proceed to substantive trial using the present study as an internal feasibility stage we will present a full power calculation in a future bid to HTA at month 18. This will include data on mean and SD of our primary and secondary outcome from the proposed pilot study. Our previous studies suggest the likely mean activity of the target population will be approximately 12 hours (with an estimated SD 9). Given a minimum clinically significant benefit is an increase of 4 hours activity and a conservative estimate of effect in the 0.3 to 0.4 range our current estimate would be that a trial with a sample size of approximately 300 cases would have sufficient power to provide a definitive test in a substantive trial. On this basis if it is decided to use the present study as an internal feasibility phase it is placed to be able to recruit between a third and a half of the participants required in a substantive trial. If not it can make a significant contribution to suggesting effect size as a significant external pilot study.

8. Statistical analysis of outcome: The main aim of the pilot project is to undertake feasibility studies. The criteria for the first phase are therefore the ability to successfully recruit a sample of suitable cases. Analysis of baseline data of the first phase aims to describe the mean and SD of the primary and secondary outcome measures to prepare a definitive sample size calculation.

If it is decided to set aside the results and publish them as an external pilot, the main analyses will use general linear models with the inclusion of treatment group and stratification baseline variables. The outcome variables will be checked for distributional assumptions (i.e. following a Normal distribution) and transformation will be applied if necessary,

For both the primary and secondary outcomes we will check the extent and patterns of missing data and use multiple imputation if it is felt necessary. Factors to include in the imputation model will be those that are likely to be related to the outcomes (a clinical decision) and those related to missingness (a statistical decision). The analysis using imputed data will be a secondary, sensitivity, analysis with complete case analysis being the primary analysis.

9. Economic evaluation: The estimation of cost-effectiveness, within a health technology assessment, is an iterative process (Ramsey et al, 2001). Here we aim to monitor levels of resource use and quality of life, with a view to inform the decision as to how costs and benefits would be measured as part of any future more definitive study. A preliminary within trial cost-effectiveness analysis of multisystemic social recovery CBT compared to treatment as usual will also be undertaken. In line with guidance by the National Institute of Health and Clinical Excellence (NICE, 2008) costs will be calculated from the perspective of the NHS and personal social services (PSS). A modified version of the Client Service Receipt Inventory (Thornicroft et al, 2006) will be used to monitor levels of resource use associated with both interventions (including intervention staff training and supervision, along with all visit related costs) and other NHS and PSS resource items, such as hospital admissions/visits, which may relate to the interventions in question. Appropriate unit costs (e.g. Curtis et al, 2009) will subsequently be attached to all items of resource use.

The main measure of outcome in the economic analysis will be the EQ-5D (Brooks et al, 2006) (a generic measure of quality of life) which will be assessed at pre- and post-intervention. Secondary cost effectiveness from an NHS perspective will use three outcome measures: improvement in activity (Time Use), improvement

in symptoms (CAARMS) and improvement in quality of life (QALYs). An economic model will be constructed in order to estimate both the mean incremental cost and mean incremental effect of multisystemic social recovery CBT compared to treatment as usual. If one of these options were shown to be less costly and more effective than the other then this would suggest that it 'dominates' the other, and represents a cost-effective use of scarce resources. Alternatively, the mean incremental cost-effectiveness ratio associated with multisystemic social recovery CBT will be estimated and assessed in relation to a range of cost-effectiveness thresholds. The associated level of uncertainty will also be characterised by estimating the cost-effectiveness acceptability curve (showing the probability of the intervention being cost-effective at various levels of willingness to pay for health benefits). Sensitivity analysis will also be undertaken to assess the robustness of conclusions to changes in key assumptions. The above stated analysis would be undertaken in each of the above study designs though if an internal feasibility study/external pilot were to be conducted these would be considered only a preliminary analysis and would need to be treated with caution, compared to that of a full trial.

10. Proposed outcome measures

Primary Outcome: Hours per week engaged in constructive economic and social activity. This assessment is derived from the Office of National Statistics Time Use Survey interview (Short, 2006; Lader, Short, Gershuny 2006). It assesses hours spent in a range of activities and was successfully used as the primary outcome in our MRC trial platform study (Fowler et al, 2009). Further details are provided in the appendix below.

Secondary outcomes: A well established mental state assessment will be used to assess levels of attenuated psychotic symptoms and associated psychopathology by interview (Clinical Assessment of At Risk Mental States (CAARMS). (Yung, Phillips, et al., 2006). In order to provide information on the difficulties experienced by participants in the study, the Structured Clinical Interview for DSM-IV (SCID; Spitzer et al, 1992) will be included at baseline and follow-up assessments. Emotional disturbance will also be assessed by brief self report questionnaires using the Social Interaction Anxiety Scale (SIAS; Mattick & Clarke, 1989) and Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996).

Health Economic outcomes: The main purpose is to monitor levels of resource use and quality of life, with a view to inform the decision as to how costs and benefits would be measured as part of any future more definitive study. A preliminary within trial cost-effectiveness analysis will also be undertaken. In line with guidance by the National Institute of Health and Clinical Excellence (NICE) (NICE, 2008) costs will be calculated from the perspective of the NHS and personal social services (PSS) using a modified version of the Client Service Receipt Inventory (CSRI; Thornicroft et al, 2006) and the Time Use Survey (Short, 2006). Quality of life will be assessed via the EQ-5D (Brooks, 1996) at pre and post intervention.

Assessments of moderation and mediation: Cognitive function and motivational factors are likely to play a key role in mediating the effect of therapy on outcomes. The assessments will include a brief battery of self report questionnaires which will allow key tests of mediation hypotheses to confirm or reject the role of such factors. These include the Beck Hopelessness Scale (BHS; Beck & Steer, 1988); Schedules of personal meaning and hope (Snyder et al, 1991); Schizotypal Symptoms Inventory (SSI; Hodgekins et al, In Press); Brief Core Schema Scales (BCSS; Fowler et al, 2006) and Experiential Avoidance (Hayes et al, 2004). A short neuropsychological assessment comprising the Logical Memory I subtest of the Wechsler Memory Scale, Third Edition and the Controlled Oral Word Association Test (COWAT; Benton, Hamsher and Sivan, 1994), will confirm or reject the role of cognitive function in mediating effects on therapy. Additionally, two self-reports, the Alcohol Use Disorders Identification Test (AUDIT; WHO, 1989) and Drug Use Disorders Identification Test (DUDIT; Berman et al., 2002) will measure levels of harmful drug and alcohol use and allow hypotheses regarding the effect of such use on outcome to be tested.

Participants will, if they wish, be provided with a brief report of each assessment (baseline, 9 month follow up and 15 month follow up). The report will take the form of a letter addressed to the participant which summarises the outcome of the key assessment measures. The participant will be provided with copies of the report which they will be encouraged to share with other professionals involved in their care if they wish to do so.

11. Qualitative sub study

The qualitative sub-study aims to inform the objectives of the pilot RCT in preparing for a large scale randomised controlled trial, utilising a qualitative, service user perspective. The qualitative study will be split into 2 phases. Phase 1 will assess the feasibility of trail participation from a qualitative perspective, and phase 2 will seek to gain more in-depth understanding of participant's experiences at follow up.

Phase 1 qualitative sub-study:

The objectives of the qualitative sub-study are:

1. To explore in-depth with the qualitative sub-sample issues of recruitment and retention, focusing specifically on individual experiences of participating in the pilot RCT.
2. To understand, from the participant's perspective, the level of involvement required and engagement with study tools and measures to date.
3. To analyse key variables of participants recruited to the pilot RCT to enable a detailed sampling frame to be established for phase 2 of the qualitative sub-study, and to inform sampling for the larger RCT.

Sampling: Initially, convenience sampling will proceed, recruiting to the qualitative sub-study all those consenting to be involved in the trial at baseline. Qualitative interviews will be undertaken between 1 and 3 months post-trial recruitment, in order to maximise recall of trial procedures around recruitment. Approximately 12 phase 1 qualitative interviews will be undertaken (6 from each randomised group).

Interviews: RAs will be trained and supported in qualitative interview techniques so as to elicit detailed data about the experience of recruitment, consent, and experiences of the study measures, tools and intervention, if appropriate. It is anticipated that interviews will last for no more than 60 minutes. All interviews will be audio recorded and transcribed verbatim.

Analysis: A broad thematic analysis will be undertaken in order that descriptive data from a service user perspective will be able to inform development of a larger RCT. Analysis will also describe characteristics of and differences between interviewees to enable purposive sampling for phase 2 of the qualitative sub-study, and to inform sample frame development for the larger RCT. Qualitative findings, in summary thematic form, will be utilised to contextualise and inform the pilot RCT aims of exploring recruitment, retention and acceptability of the study intervention.

Phase 2 qualitative sub-study:

This phase of the qualitative sub-study will seek to understand the narrative histories of participants, and the perspectives of users on their own subjective evaluation of their personal recovery including hopelessness, perceptions of stigma, and interpersonal functioning. The objectives of phase 2 are:

1. To explore the narrative experiences of young peoples' psychological difficulties as they understand them.
2. To understand young peoples' perceptions of their history of involvement with services.
3. To understand perceptions of treatments received as part of the research study and what impact this may not or not have made.
4. To explore hopes and fears for the future.

Sampling: A sampling frame will be established to purposively sample participants with particular characteristics, in order that maximum variation across the study sample is achieved. Key constituencies of the sampling frame are likely to include randomised group, age, symptoms (i.e. severity), family background and previous history, gender and ethnicity. We will also attempt to ensure that the most vulnerable young people are recruited, including looked after children and those not in education or employment (NEET). This will ensure that a wide range of views and experiences are captured in phase 2 of the qualitative study. It is estimated that 16 study participants will be recruited for the qualitative sub-study, approximately 8 participants per randomised group.

Participants agreeing to take part in this further in-depth interview will sign a separate consent form, and will be interviewed at trial follow up (9 months)

Interviews: Qualitative interview guides will focus on key topics, but be flexible in allowing participants to explore their experiences in an open ended narrative manner that is meaningful to them, within the context of their own mental health experiences. Particular efforts will be made to attempt to elicit in-depth narrative accounts for detailed analysis.

Analysis: An Interpretative Phenomenological Analysis (IPA) approach to analysis (Smith et al, 1999. This approach will allow individual backgrounds to be analysed as a context to experiences. All interview data will be audio recorded and transcribed in full, using digital transcription software in order that nuances of speech are captured. Data will then be analysed line by line and thematically coded for meaning, aided by the computer

package NVivo 9. The coding will give an overview of themes and issues for each participant, but analysis will be presented in both summary thematic (across the sample) and individual case study format, in order that the context of individual experience is not lost. Data analysis will be led by CN, an expert in qualitative methods, with input via a qualitative analysis study group, to include (CS, RB and service users). Coding and case based analysis of individual interview transcripts will be undertaken independently by members of the analysis study group, with a proportion (approximately 50%) separately analysed to allow for comparison, verification and eventual consensus of analysis. Independent service user involvement will be sought from a service user not participating in the pilot study to discuss emergent analysis results and verify study findings. Transparency in qualitative analysis will be strived for at all stages, thus a detailed audit trail of analysis procedures will be maintained. Emergent analysis will be utilised to inform purposive sampling of participants to the qualitative study, thus analysis will shape and define the eventual total qualitative sample. Qualitative findings, in summary thematic and individual case study form, will be utilised to contextualise and inform the pilot RCT aims of exploring recruitment, retention and acceptability of the study intervention.

12. Research Governance

Sponsorship: Norfolk and Suffolk NHS Foundation Trust will sponsor the study.

Data Monitoring Committee: We will assemble a Data Monitoring Ethics Committee (DMEC) that will have access to all trial data. The DMEC will have a key role in considering interim analyses and data review from the pilot trial and in advising the Trial Steering Committee (TSC) on the decision to regard pilot data as an internal pilot and proceed with an application to a full trial, or to set aside the data and analyse and write up the pilot as an external pilot. The DMEC will also consider whether any interim analysis is warranted, review data from any analysis and consider requests for data release, again acting to advise the TSC on these issues. Finally, the DMEC will be tasked with advising the TSC on any ethical or safety reasons why the trial should not continue giving due consideration to the safety, rights and well-being of participants.

Membership of the DMEC will be completely independent of the study and comprise of at least two clinical academics with experience of trials, a service user with experience of research and independent statistician. Professor Tony Morrison (who was chief investigator of EDIE 2) has agreed to be chair of the DMEC. This group will be recruited to meet before the study begins with the chief investigator to consider the activity of the DMEC and set an agenda of meetings of sufficient frequency and at strategic points to fulfil the duties and responsibilities of the DMEC. Additional travel and meeting expenses have been added for this committee which we have budgeted three meetings.

Trial Steering Committee: The TSC will meet every six months. It will be closely linked to a service user steering committee in the early stages of the study. Professor Alison Yung (who is an established international expert in this area) has agreed to chair the TSC, Rory Byrne a service user and scientist in Manchester will sit on both this committee and on the service user steering committee the protocol has already been discussed with him. Other recruits to this committee will be a further service user, and Professor Swaran Singh from University of Warwick and Professors Max Birchwood and Stephen Wood of Birmingham who all recognised experts in this field and will lead a further sites in the West Midlands if the trial proceeds to full. The PIs trial manager and representatives from all the participating sites will also sit on the TSC.

The role of the TSC is to provide overall supervision for the trial, concentrate on the progress of the trial and adherence to the protocol and provide advice through its independent chair. The ultimate decision for deciding progression to full trial which may involve the use of the data from the present project as an internal pilot and the continuation of the trial at any time in the course of the study lies with the TSC, advised by the DMC. The TSC will report to the sponsor and the Health Technology Assessment Programme (funder).

13. Project timetable and milestones

Prior to start of the study: Preparations to be made before the beginning of the study will be a) obtaining ethics and research governance approvals (b) publicising the study to senior managers, clinicians and service users in the sites participating in the study (c) recruiting the first three members of staff beginning with the trial manager who will participate in the recruitment of other staff. (d) trial therapists will be identified before the start of the study and attend a series of pre study workshops discussing client information and undertaking their own pilot cases using the therapy manual.

The first 3 months (study set up period): The study will begin when the senior RAs are recruited in each centre. The process of publicising the study will continue. Therapy procedures and the procedures for optimal

treatment as usual will be finalised. Training will be provided for therapists in delivering the intervention. Training will be provided for the RAs in undertaking assessments.

Pilot study recruitment (Months 4 to 9): In month 4 recruitment to the pilot study will begin in teams in Norfolk and Manchester. Randomisation will follow gaining informed consent and an initial interview. Recruitment will continue for 6 months and patients will be followed up initially at 3 months.

Pilot study follow up assessments (months 7 to 12): Participants in the pilot study will initially be assessed at 3 months. At this point we will assess the feasibility of proceeding to a full trial, based on recruitment at this period. Pilot study follow up assessments will end in month 12(?15). Qualitative interviews will be undertaken at baseline and at three months.

Decision making and preliminary pilot study write up: (months 12 to 18): In months 13 and 14 we will consult the DMC as described above in order to decide whether to regard the data collected as an internal pilot and proceed to a full trial application or to set aside the data and change the protocol and write the preliminary pilot phase up as an external pilot. We will present to the HTA data on recruitment and retention in the pilot phase in order to obtain ratification of the decision and if necessary guidance. If the decision is not to proceed to a full trial we will make alterations to the inclusion criteria and changes to the protocol suggested by the preliminary pilot phase and continue recruiting to the study from the above 3 month stage reviewing again in between months 24 and 30.

At months 24 to 30: there will either be a repeat of the decision making and preliminary pilot stage as above for the second phase pilot. Or a decision will have been made to continue with data collection as the internal pilot for a substantive trial in which case a submission to HTA for a fast track full trial will be made at 18 months with data continuing in the present study till month 30 which will allow time for the team to continue with the project until a decision on funding is made.

At month 30: the project data collection will finish and depending on the decisions of the above committees according to the qualitative and quantitative data. The data will either be written up as a substantive pilot project involving 100 cases, as a series of external pilots of 40 and 60 cases respectively or it will be the first phase of a larger trial which will continue with another centre depending on power calculation.

14. Team expertise: This project draws together a team of investigators who have considerable experience in designing, running and utilising complex pilot studies of this type. The applicants have considerable experience of working together on previous projects and have established track records in engaging young people in research, and developing innovative psychological interventions.

15. Service Users: We have consulted service users in the course both of preparation of the outline and the full proposal, and we are also planning considerable input to the main study. In the course of preparing the outline and full proposal, we consulted service users in the Norfolk Early Intervention Service regarding the study, focusing especially on the feasibility and acceptability of the intervention and how best to implement it. The main topics in our consultation, which has informed preparation of the proposal and decisions about the intervention, have been the content, presentation and acceptability of the intervention, best methods for recruiting to the trial, and the best way of engaging service users in the research process.

We plan to hold a half yearly service user and carer researcher steering group. This will alternate with the main study steering group, and representatives of the service user and carer steering group will sit on the main study steering group. We propose a minimum membership of this group of 4 service users and 2 carers, half recruited from among current EIS service users and half via the MHRN service users and carers who have substantial experience in contributing to research and service development. We will also consult this group via electronic means about the key decisions in the study. Throughout we will consult this group on final version of study materials, interventions and methods, on methods of publicising and recruiting to the study, and on interpretation and dissemination of our findings. The Rethink Young People's Panel, a group of around 10 young service users aged between 16 and 25, many with experience of psychosis, will also be involved on a regular basis to advise on issues emerging from the research fieldwork. The panel meets on a regular basis and its members offer experience of reviewing reports, national policy and research studies concerning young people's mental health. Some of the group have attended writing workshops or have been trained in presentation skills. The team will draw on this expertise in ensuring that the outputs of the study are relevant and accessible to young people, their families and carers.

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Appendices

a) Further details on the potential progression to the full trial

We suggest that the suitability for progression to a substantive trial should depend on whether the data collected in the early phase of the present study meets specific objectives for recruitment and suitability criteria. These are: a) *If recruitment within the first year of the present study is within 20% of planned; b) if the assessments achieved are judged as suitable and the data of high quality; c) if the qualitative study suggests inclusion criteria and procedures are appropriate; d) if the intervention is well received; e) if we are not excluding potentially important subgroups and f) if there are no other substantial changes to the present protocol we would regard the data collected in the pilot phase as suitable for inclusion in a substantive trial as an internal feasibility phase.*

A substantive proportion, if not all, pilot data which would be collected during the present project may then be suitable to be used as an internal feasibility phase of a substantive trial. We have increasing confidence that we can complete a successful trial, however, it is sensible to be prudent. We therefore suggest that the decision about suitability for including pilot data within any future substantive trial and the progression to such a trial should be dependent on checking the results of the proposed qualitative study and the quality of the empirical data collected in the early phase of this project against the above criteria. This data and the criteria can then inform the decision making of the Trial Steering Committee (TSC) who will make the decision on progression in liaison with the Data Monitoring and Ethics Committee (DMEC) and the Service User Advisory Committee (SUAC) and review this at key decision points in the milestones. We highlight a decision making and research governance process, and potential progression below and suggest specific milestones later in the protocol.

By the end of year 1 of the study we aim to complete the qualitative project and recruit at least 40 participants: 20 treatment and 20 controls and complete baseline assessments and a 3 month follow up. At 12 months we plan to examine this data and evaluate the suitability of progressing to a substantive trial using the data collected as an internal feasibility stage of a substantive trial. In months 13 and 14 a decision will be made by the Trial Steering Committee who will assess the data collected with respect to the criteria above, and will consult with the DMEC and the Service Users Advisory Committee (SUAC) to decide whether the data is a) suitable for inclusion as the internal feasibility phase of a substantive trial; or b) whether it would be best to complete the study as an external pilot; c) whether to change or adapt the protocol and then to continue recruitment or d) to stop the project.

a) If the decision is to proceed to a substantive trial using the pilot data as an internal feasibility pilot. We would continue to collect data following the present protocol. But at the same time aim to proceed to present to HTA by month 18 a fast track full trial application which will include the data on recruitment and retention in the pilot study. This would allow decision on an extension to the present project to complete a substantive trial involving inclusion of two extra centres in the West Midlands (Birmingham and Coventry). This would keep the team and procedures together while continuing to recruit a further 60 participants over the subsequent 18 months and awaiting a decision on further funding. This also allows the possibility of analysing the data as a stand alone external pilot comparing 50 versus 50 as originally planned if the committee decision is not to fund a full multicentre substantive trial.
b) If the collective decision by the TSC is not to proceed to a full trial and that instead alterations to the protocol are required. We will then regard the results of the first 40 participants as an external pilot and set this aside and write it up as such, together with the qualitative studies. The TSC would then seek guidance from the DMEC and SUAC and HTA who together with the research team can agree any changes to protocol which may be required. We would then proceed to recruit a further 40 participants over the next 12 months checking again the data against the quality criteria at month 24. If this data is then judged as suitable we would then proceed to proceed submit a full trial application using these cases as an internal feasibility stage while recruiting the final 20 participants to the end of treatment as planned similar to described in a).
c) If recruitment falls 20% below planned rates at key time points of 12 and 24 months or if procedures are otherwise judged as not feasible by the TSC we will seek advice from the DMEC and the SUAC and HTA as to whether it is most appropriate to stop the project altogether and allow for contracts to expire.

b) Further clarification of the use of the time use assessment interview to assess primary outcomes

In this study we use number of hours per week engaged in structured activity (which includes time spent both constructive economic activity: e.g. work; education, childcare and in structured activity e.g. chores, sports, voluntary work, structured social activity) as our primary outcome assessment of social functioning. We assess time spent in activity using the Time Use Survey (Lader, Short, Gershuny, 2006) which is the standard Time Use interview as used in the Office of National Statistics UK Time Use Survey. The reason for this choice of assessment it that one of the identified problems in undertaking research on social recovery has been the lack of a valid, sensitive and reliable outcome assessment. While there are a number of widely used scales of quality of life and social functioning used with people with mental illness these have several problems. First, such scales often lead to arbitrary definitions of groups based on social functioning or quality of life scores. For example, it has been recently highlighted that identifying groups of young people with severe mental illness as socially impaired on the basis of arbitrary scores on two widely used social functioning scales (the QLS and SOFAS) resulted in group identified as social impaired in which 17% were working full time (Lin et al, 2011). This is contradictory as working full time is often taken as a marker of full social recovery. This may arise from the well recognised problem that many so called social functioning scales often confound symptom assessments (of depression and negative symptoms) with social outcome so that people who make social recoveries despite their symptoms may be wrongly identified. Another problem with many of the present scales of social functioning is that they are relatively insensitive to important clinical changes, and changes in scores difficult to interpret. Defining social outcome based on hours in activity overcomes these issues and provides an assessment with direct face validity to users, clinicians and service managers and commissioners based on hours in constructive economic activity, or structured activity.

The interview assessment is well established and available from the ONS time use survey (Lader, Short, Gershuny, 2006), which itself derived from an extensive research portfolio of studies on time use in the UK and

internationally. In work carried out as part of our MRC trial platform we showed that the Time Use Assessment shows good reliability with other well known scales of Quality of life and social functioning but is less confounded with symptoms (Fowler et al, 2009) . It is also a scale which users and other interested parties find readily and directly understandable. Focus groups of clinicians and users we carried out as part of our MRC trial platform study have reached a consensus agreement that for this population a 4 hour gain in structured activity represent an agreed minimum clinically significant gain. We have shown the scale to be sensitive to change in its use as primary outcome in our MRC trial platform study (ISREP; Fowler et al 2009).

As a result of a series of studies we have completed since the outline proposal was submitted, we now have data which allows comparison of clinical groups of young people with severe mental illness with young people from the general population and provides us with an empirical basis to identify a socially disabled group at risk group we wish to target in a trial. In table 1 we show data on time spend in constructive economic and structured activity comparing different samples of young people with ultra high risk symptoms (from the EDIE II trial) with young people with first episode psychosis (from the National Eden study) with young people with chronic psychosis and social disability (from ISREP) with age matched data from the ONS time use survey which allows a comparison with 6000 age matched young people in the general population. As can be seen the ultra high risk group has a similar relatively low level of activity to the samples, first episode psychosis and even chronic psychosis samples. This is suggestive of the emergence of social disability at an early stage in the evolution of severe mental illness and consistent with long term follow up studies. However, large standard deviations indicate considerable heterogeneity in all the samples showing what a large range of functioning from normal patterns of activity to very low patterns of activity. The group at most risk have early signs of social impairment and have low patterns of activity at an early stage of disorder (Lin et al, 2011). It young people who have severe and complex mental health problems in association with low activity we wish to target.

Our analyses suggest that a useful cut off for isolating a socially disabled group using the Time use Assessment may be performing at a level of less than 30 hours per week total structured activity. As can be seen above this is less than half the mean level of functioning of young people in the normal population. Analyses of the EDIE 2 trial data and referral patterns to our existing clinical services suggest that this is a population of young people who have severe and complex needs which are not met by current interventions, but are a group which are help seeking and already being referred into research trials and clinical services (though often at present excluded). Several recent national reports have highlighted the unmet needs of this population (Singh et al, 2010; DoH, 2008) and our research and clinical experience has already shown we can recruit samples into studies. Our analyses of the MRC EDIE 2 trial data showed that 122/205 (60%) cases in EDIE were functioning at this level with structured activity below 30hrs per week. This subgroup are engaged at a very low level of activity (mean less than 15 hours total structured activity in a week) and they are a more homogeneous sample (Mean 13.96 SD = 8.71). Our established clinical services for detection of cases at risk of psychosis which we successfully used in the completion of the EDIE 2 multicentre trial can therefore provide a large source of the referrals for this study. In addition we also intend to recruit young people who have severe and complex mental health problems and social impairment but who have less severe attenuated psychotic symptoms (and thus were excluded from EDIE 2 and early intervention services as they do not meet symptomatic criteria for an At Risk Mental state or Psychosis). We get many referrals to our existing clinical services of this type. In Norfolk we ran a pilot service for young people aged 14 to 18 which included this group. This clinical pilot has been highlighted as an example of clinical excellence in engaging and treating young people (Joint working at the interface, 2011) and shown that such cases are available for recruitment as they are commonly referred to early detection and intervention services for psychosis (though currently excluded). Also this group includes young people with severe and complex mental health problems who are not in education, employment and training (NEET) who are identified as being at high risk by statutory agencies and are therefore a priority group to target. The group has a similar levels of time use to that of the EDIE 2 sample (mean less than 15 hours, SD 9).

In summary, the Time Use Survey is a well known and validated instrument. We have shown it is acceptable, reliable, and sensitive to change and thus highly suitable to be used as the primary outcome to assess social functioning levels in a randomised controlled trial involving young people with severe and complex mental health problems and social impairment.

Table 1. Comparison of Constructive Economic and Structured Time Use across studies – Mean hours per week (SD)

	Constructive Economic	Structured (without hobbies)
EDIE Young people with Ultra high risk symptoms (N = 288)	25.11 (27.05)	30.67 (27.81)
EDEN Young people with first episode psychosis (N = 1027)	17.23 (23.80)	25.44 (27.10)
ISREP Young people with chronic psychotic disorder and social impairment (N = 77)	12.43 (17.05)	19.66 (17.54)
ONS Aged matched young people in the normal population (N = 6000)	50.93 (25.40)	64.18 (27.22)

Note. Constructive Economic Activity = work, education, voluntary work, childcare & chores

Structured Activity = Constructive Economic Activity plus leisure and sports activities

c. Further detail regarding the proposed qualitative study

The proposed methods for collecting qualitative data from young people draw on earlier studies of young people's experiences of mental health services and participating in research. These studies have highlighted the importance of flexible data collection processes; of researchers being skilled in engaging with and working at the pace of young people often presenting with multiple difficulties and complex care histories (Street & Svanberg 2003), of the ethical implications of researching vulnerable young people (Taylor et al 2010), and of being able to work across and gather information from a range of different agencies (Garcia, Vasiliou & Penketh 2007). Studies have suggested the importance of service user involvement in understanding the views of those with emergent signs of severe mental illness (Hardy, Dickson, & Morrison, 2009) and in this study, we intend to involve service users at all project stages as much as possible.

A qualitative approach is particularly suited to taking the viewpoints of young people. Interpretative Phenomenological Analysis is the method chosen for the proposed research, as it is focused specifically on the individual experiences contextualised within an understanding of young peoples' own lifeworlds. This approach had been successfully adopted by comparable studies, seeking participant views of early intervention services (O'Toole, et al. 2004). These and other research studies involving young people have also drawn attention to the importance of providing young people with detailed but accessible information about the study - what it entails, its aims, how confidentiality will be protected and how findings will be used. All of these issues have been fully accounted for in our approach.

Data gathered from the qualitative sub-study of the pilot RCT will inform suggestions about improvements and alterations to the recruitment techniques, measures and tools utilised as part of the study, and may potentially suggest alterations to the CBT intervention. A further outcome of the qualitative sub-study will be to define the sampling frame for the larger embedded qualitative study planned as part of the future RCT, by analysing variability across the recruited pilot sample. The pilot qualitative study will begin to explore experiences of the intervention, thereby suggesting major themes for exploration at interview in the embedded qualitative study of the larger RCT. Further details are supplied below.

d) Further justification of selection of age bands and consider the ethical implications of recruiting children and young people

We will recruit only young people aged 16 and above. This is appropriate our experience suggests that young people aged above 16 would be most suitable for this intervention and the assessments we plan to use are validated for use with over 16 year olds. Also, our analysis of the current numbers of young people aged under 16 being referred to our existing services (which have a catchment of 14 to 35) indicate that the numbers of children we could identify as being at risk using the present criteria below this age would be very low.

Our approach to recruitment, conducting assessments and carrying out intervention has carefully considered the ethical implications of this study. The specific adaptations we have made include the need for a flexible approach; to use researchers trained and experienced in engaging with and working at the pace of young people with mental health problems; to ensure that all information materials about the study are 'young person friendly' and are accessible to them and their parents and carers. Particular attention will be paid to gaining consent for their involvement in the study. A detailed research pack including information sheet and consent forms will be given to the young person by a member of staff familiar/already working with them, e.g. their care coordinator. This staff member will liaise with the research team regarding the young person's capacity to give informed consent and seek consent from a person with Parental Authority should this be required. The pack will explain the benefits and known risks of the study and will emphasise that the young person's involvement in the study is entirely voluntary, will not affect the treatment and care offered to them in any way and that they can withdraw from the study at any time. A research assistant carefully trained in procedures for eliciting informed consent will work with the care coordinator throughout this process.

All assessments will be conducted in appropriate and accessible venues that suit the needs and preferences of the young people. They will be scheduled at times convenient to the young person and if they wish, a family member, trusted friend or member of staff already known to the young person, can be present to support them if they wish. Young people will also be given the opportunity to comment on the write-up of their interview and will be reassured by the researcher that in all study outputs, data will be written up in such as way as to ensure that neither they nor their family can be identified.