# Quality and Effectiveness of Supported Tenancies for people with mental health problems (QuEST): Workpackage 4
# Protocol (v.2 27.02.15)

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## BACKGROUND

The NHS Hospital Plan of 1962 heralded the process of deinstitutionalisation in England and Wales and the development of community based mental health care (Ministry of Health, 1962). The number of long stay beds has reduced from over 150,000 in 1955 to less than 3,000 today (Shepherd and MacPherson, 2011). Subsequent policy has moved the responsibility for provision of mental health supported accommodation from Regional Health Authorities to Local Authorities and local NHS commissioning, with an increasing emphasis on partnership working between statutory, voluntary and independent sectors (Department of Health and Social Security, 1981; Department of Health, 1990a; Department of Health, 1998; Office of the Deputy Prime Minister, 2002).

In England, around a third of working age adults with severe mental health problems reside in supported accommodation provided by health and social services, voluntary organisations, housing associations and other independent providers. These include nursing and residential care homes, group homes, hostels, blocks of individual or shared tenancies with staff on site, and independent tenancies with "floating" or outreach support from staff. Local statutory community mental health services provide care co-ordination and clinical expertise to the residents and staff of supported accommodation projects through the Care Programme Approach (Department of Health, 1990b). In 2006 around 12,500 people with mental health problems in England were in a nursing or residential care home (National Statistics, 2006) and around 40,000 were receiving floating outreach (Department of Community and Local Government, 2006). The costs vary from around £150 per week for floating support to around £500 for residential care. The annual cost to the health and social care budget is therefore hundreds of millions of pounds.

The majority of those who require these services have complex mental health needs and functional impairments that impact on their ability to manage activities of daily living. Many experience ongoing symptoms of their illness despite medication, and impairments in cognition associated with long term severe psychosis that reduces their motivation and organisational skills (Holloway, 2005). They may require assistance to manage their medication, bills, personal care, shopping, cooking, cleaning and laundry. However, the majority have been shown to be able to sustain community tenure with support and many gain skills and can manage with less support over time (Leff and Trieman, 2000; Trieman and Leff, 2002). Nevertheless, the vast majority are unemployed and many are socially isolated and do not participate in civil and political processes (Boardman et al., 2010). In short, despite the move towards community based care, this group remains one of the most socially excluded in society (Social Exclusion Unit, 2004).

Supported accommodation services have a very important role in assisting people with complex mental health problems to live in the community, but despite this and the large resources dedicated to these services, there has been very little research to investigate their effectiveness (Fakhoury et al., 2002). As well as concrete outcomes such as the proportion of service users that move on to less supported settings, it is not known whether these services are intervening to improve the social inclusion of their users, though one qualitative study suggested that staff felt this was important (Hogberg et al., 2006). A review of floating outreach commissioned by the

Department of Communities and Local Government (2006) commented that "Success cannot be measured in terms of the number of clients who no longer require support. Factors such as sustained tenancies, rates of hospital readmission, attendance at day centres, voluntary work, training courses and employment should be taken into account" and concluded "there is a need to undertake more comprehensive and longer term studies to evaluate the impact of floating support services."

The only survey of mental health supported accommodation to be carried out in England (led by co-investigator SP) found few differences in the characteristics of service users in different types of setting or in the support offered (Priebe et al., 2009). The survey sampled 12 nationally representative regions, identified a total of 481 projects of which 250 were randomly sampled. Of these, 153 responded to a postal survey; 57 were nursing/residential care homes (with a mean 16 residents), 61 were individual or shared flats with on-site staff support (with a mean 13 service users) and 30 provided floating outreach to a mean 34 service users in their own independent flats, usually rented from the Local Authority or a Housing Association. Staff provided anonymised data on 414 service users. The majority were male, 80% had a diagnosis of a psychotic disorder and 48% also had a substance misuse history. There were no differences in service user characteristics between service types. Around 40% of those in supported housing or receiving floating outreach were participating in some form of community activity (compared to 25% of those in residential care) but similar numbers of hours were spent by service users across all settings in education or work (mean 13 hours per week) and only 3% were in open employment. Staff made contact with users on average six days a week in supported housing and four days a week in floating outreach services. Between four and six service users (18-25%) moved on from each service annually. Although residential care settings had a higher proportion of trained mental health staff than the other services, almost all service users in all types of setting were prescribed medication and all services provided support with personal care and activities of daily living. The costs of these services appeared to be driven by the local tradition of provision rather than clinical need. Shepherd and Macpherson (2011) have also commented that the development of local supported accommodation provision appears to be largely determined by history, the sociodemographic context of the area and the support available from primary care and secondary mental health services.

We recently carried out a qualitative study of staff and service users of supported accommodation services across England and found few differences in the overall aims and type of support provided by supported housing and floating outreach services. Staff of both types of service reported that they aimed to support service users to maintain and increase their confidence and skills in order to achieve the highest level of independent living in the community. They reported that they achieved this though prompting and supporting service users to practice and gain confidence with these skills incrementally to the point where they could manage them independently. Staff of both types of service reported providing support with activities of daily living (self-care, laundry, housework, shopping, cooking, paying bills and managing finances), managing medication, community activities, keeping appointments and managing risk and safety (Sandhu et al, paper in preparation).

Although these previous studies do not suggest that there are major differences between the content of care provided in supported housing and floating outreach services, most areas of the UK have supported accommodation systems where service users move to more independent settings as their skills improve (from residential care to supported housing and from supported housing to floating outreach). This allows for graduated "testing" but many users dislike repeated moves. Recently, there has been increased investment in supported flats rather than group settings since many services users prefer their own independent living space (Tanzman, 1993; Massey and Wu, 1993). A number of studies have identified discrepancies between service user and staff views on the level of support required, with service users tending to prefer more independent accommodation (Minsky et al., 1995; Piat et al., 2008). Family members also tend to prefer their relatives move to staffed environments (Friedrich et al., 1999). An important criticism of staffed settings is the maintenance of institutional regimes and impaired facilitation of service users' autonomy through over support and a poor rehabilitative culture (Ryan et al., 2004). Conversely, some service users and family members have reported that independent tenancies are socially isolating (Ryan et al., 2004; Walker et al., 2002).

There have been no trials investigating the effectiveness of supported accommodation services for people with mental health problems (Chilvers et al., 2002) and other types of studies investigating these services are few and poor in quality (Fakhoury et al, 2002). The paucity of research reflects the logistic difficulties in researching this area. Randomisation to different types of housing support may be resisted by clinicians who feel that service users require a staged process, moving from higher to lower supported settings as their skills and confidence increase, and by service users with clear preferences for particular services. It also seems that the availability of supported housing stock is more influential than clinical need in determining accommodation allocation.

These clinical and housing constraints mean, however, that we simply do not know whether or not individuals are following the most cost effective routes to independence. In short, we do not know whether more tailored support delivered to service users in their own homes through floating outreach is more acceptable, more individualised and more cost-effective than a standard level of support provided in staffed facilities. However, in the US, the "Train and Place" approach (which provides a constant level of staffing on-site to a number of apartments with the expectation of service users moving-on as they gain independent living skills) has been compared in a quasi-experimental study to the "Place and Train" approach (which provides floating outreach support of flexible intensity to service users living in an independent, time-unlimited tenancy) and found to facilitate greater community integration and service user satisfaction (Corrigan et al., 2005).

In summary, there is no clear evidence as to whether the supported housing model (offering time limited, building based support) is more or less effective than the floating outreach model (offering flexible, visiting support to people in a permanent independent, tenancy). This clinical equipoise therefore justifies assessment through a randomised controlled trial, but, given the logistic difficulties outlined above, there is first a need to assess the feasibility of conducting such a trial.

**OBJECTIVE**
This study aims to assess the feasibility of a randomised evaluation of two models of supported accommodation for people with mental health problems.

**DESIGN AND SETTING**
We will assess the feasibility, sample size and outcomes for a large scale trial to compare the clinical and cost-effectiveness of two commonly used models of mental health supported accommodation; supported housing and floating outreach.
We will include services that provide both types of supported accommodation in three sites where the study team has good links (North London - Camden and Islington; East London - Tower Hamlets, Newham, Hackney; Gloucester and Cheltenham or Belfast - TBC).

**INCLUSION/EXCLUSION CRITERIA**
All adult mental health service users in the three study sites referred to either supported housing or floating outreach services will be eligible for inclusion, provided they are potentially eligible for both supported housing and floating outreach services. Those who do not meet Local Authority eligibility criteria for an independent tenancy from where they could receive floating outreach services will not be eligible for the study. In general, adult mental health service users will be subject to CPA and have an allocated care co-ordinator. Those service users unable to give informed consent will be ineligible. Given these services provide for users who are considered able to manage in such settings, it is unlikely that many will lack capacity to give consent.

Each of the three study sites has a system for referral of service users to local supported housing and floating outreach services which is co-ordinated by specific individuals. All those referred will be considered for potential participation in the study. The Chief Investigator and other members of the study team will meet with the staff involved in receiving referrals for supported housing and floating outreach services in each area to explain the purposes of the study, to clarify the process for referral to these services and the relevant personnel with whom the study team will need to liaise during study recruitment. A researcher (SS, JK, PM) will be based at each study site. They will meet with the key personnel involved in the referrals systems in each site. They will also meet with clinicians who make referrals to supported housing and floating outreach services, such as care co-ordinators, care managers and other clinicians. They will explain the rationale for the study. They will make weekly contact with the referrals co-ordinators at each site to gain details of any new referrals for supported housing or floating outreach services. They will then contact the referring clinicians to discuss whether the individual referred might be considered for participation in the study. Where the clinical team feel that it is clinically inappropriate for the person to be approached about the study, or where they feel that the person's clinical needs would make randomisation inappropriate, that individual will not be contacted by the study team.

**ALLOCATION OF PARTICIPANTS TO TRIAL ARMS**
Across the three study sites there are estimated to be at least 50 supported housing and 12 floating outreach services offering support to over 1000 service users in total. Based on data from our previous survey of supported accommodation services in these areas, we estimate an average 20% service users will move on each year from

each service leaving vacancies for 200 new referrals per year across the three sites. We aim to recruit and randomise 60 participants from across the three sites and have allowed 15 months for recruitment. A main aim of the feasibility trial is to establish whether randomisation to different types of supported accommodation is possible, including its acceptability to service users, clinicians and service providers and its feasibility given the complex logistics involved. A relevant comparison here is with the "Individual, Place and Support" model of supported employment. Though originally considered too logistically challenging for evaluation through randomised controlled trials, such trials have now been carried out successfully (Crowther et al., 2001; Twamley et al, 2003; Burns et al., 2008). Similar challenges may apply here. Service users do not necessarily have much control over the type of supported accommodation they are referred to. Clinicians and providers tend to steer the process and may be anxious about a service user's suitability for one of the two types of supported accommodation we propose to compare. This is not a unique problem in that professionals and clinicians often have opinions that are not evidence based about what is best for their patients. However, we will need to engage with key individuals in each region to agree acceptable protocols. Where there is agreement for a participant to be randomised and they have given their informed consent, they will be randomly allocated on an equal basis to either the supported housing service or the floating outreach service. Randomisation will be conducted independently of the research team by a statistician from the Pragmatic Clinical Trials Unit based at Queen Mary's University London. Randomisation will be stratified by site to ensure equal numbers of participants are allocated to both types of service within and across sites.

**COMPARISON SERVICES**

Supported housing services provide a constant level of staffing on-site to a number of service users living in individual or shared tenancies with the expectation of move-on within two years. Floating outreach services provide support of flexible intensity to service users living in an independent tenancy which is time-unlimited. Current evidence does not suggest that there are major differences in the content of care and support provided by these two supported accommodation models.

The **content of care delivered by both types of service** will be assessed during the feasibility trial 6 and 12 months after participant randomisation using:
a) a standardised quality assessment tool completed by the supported accommodation service manager through a face to face interview with the researcher. This tool was developed by the authors and subsequently adapted for supported accommodation services during an earlier phase of this programme of research (QuIRC; Killaspy et al., 2010). Managers will also be asked to complete a proforma to provide descriptive data on the service. We will complete these tools once for each service, 6 months after the first participant is randomised to that service.
b) a proforma to collect information about the number of contacts made by staff of the supported accommodation service with service users over the previous 3 months. This information will be collected from service users and corroborated with staff and case note review 6 and 12 months after randomisation.
c) a standardised measure that assesses the amount and complexity of activities service users have engaged in over the previous week (the Time Use Diary, Jolley et al., 2006). This measure will be completed separately by a staff member who knows

the participant well (such as the participant's keyworker) and the participant through face to face interviews with the researcher, 6 and 12 months after randomisation.

## OUTCOME ASSESSMENTS

The main aim of this study is to assess the feasibility of a large scale randomised controlled trial assessing two existing models of supported accommodation. We will therefore assess a number of aspects of feasibility: the number of referrals to the trial; the number recruited and randomised; attrition (i.e. the number who withdraw consent to continue with the research, decline to move to the allocated service, or cannot be located at follow-up); and the time from recruitment to moving into either type of supported accommodation. Data on these areas of uncertainty will inform the feasibility of a larger scale trial including the rate at which recruitment could take place and the likely number of sites required. If we are able to recruit our target of 60 participants (who would all be randomised) from three sites over our 15 month recruitment period then we will consider a large scale trial to be feasible.

We will ask those who are recruited whether they have any preference for either of the two models (and if so, which) at baseline. We will also ask the referring clinician if they have any preference for the type of supported accommodation their client receives as part of the staff baseline interview. We will ask the service user and their care coordinator/keyworker to give their feedback about their experiences of randomisation and views about the trial using a simple proforma which will be included in the 12 month follow-up interviews. In addition, we will ask other key individuals involved in the supported accommodation referral process to give their feedback using the same proforma.

We will ask service users who do not wish to be randomised (and clinicians who do not agree for their service users to participate) their reasons for this. We will invite up to 60 service users in this group to participate in a naturalistic follow-up to determine their outcomes over time. If they are willing, we will collect the same baseline and outcome data as for randomised participants from staff and service users.

### Baseline assessment

Before randomisation we will collect data on participants' age, gender, ethnic group, diagnosis, length of contact with mental health services and previous type of accommodation from staff and case notes. We will also assess their social function using the staff rated Life Skills Profile (Parker et al., 1991) and adjust for this in our analyses.

### 12 month outcome assessment

We will test the feasibility of collecting the following outcomes for service user participants at 12 months follow-up. These outcomes include those suggested by staff and service users in our previous qualitative study and those suggested in the background section of this protocol. Where relevant, assessments will be carried out at baseline as well as 12 month follow-up (denoted by *) in order to assess for baseline scores and adjust for these in our analyses. Where we have more than 30% missing data we will consider that outcome to be unfeasible to include in a larger trial. If there is more than 10% missing data for any outcome (but less than 30%) we will consider if there are ways to improve the response rate.

***From service user interviews:***

- Mental health **(Brief Psychiatric Rating Scale*** [Overall and Gorham, 1962]**)**
- Quality of Life **(Manchester Short Assessment of Quality of Life*** [Priebe et al., 1999])
- Engagement in community activities - proforma (leisure, education and employment activities) and **Time Use Diary*** [Jolley et al., 2006]
- Social inclusion (**SIX*** [Priebe et al., 2008] plus items from **Manchester Short Assessment of Quality of Life*** [Priebe et al., 1999] such as friendships and relationships with family)
- Costs of care (**Client Service Receipt Inventory*** [Beecham and Knapp, 1999]) – this includes details of staff contacts, hospital admissions, outpatient and other contacts with health services.
- Satisfaction with service (**Client Assessment of Treatment** [Priebe et al., 1995])
- Engagement with services/therapeutic alliance (**Scale to Assess Therapeutic Relationships in Community Mental Health Care** [McGuire-Snieckus et al, 2007])
- Service user attitude towards moving on successfully (single question "I expect to become more independent in the next two years)

We estimate the service user interview will take around 30 minutes.

***From case notes and interviews with key staff:***

- Number and length of any **hospital admissions** (including those for mental health and physical health problems)
- Indicators of community placement breakdown (**eviction notice or loss of tenancy**)
- Indicators of difficulty managing the tenancy (**rent, service charge or other bill arrears, recorded complaints from neighbours**)
- Evidence of greater independence (**for those in supported housing, move on to less supported accommodation without placement breakdown or hospital admission; for those in floating outreach, managing with less support without loss of tenancy or hospital admission)**
- Staff attitudes towards service user moving on successfully (single question "I expect this person to become more independent in the next 12 months")
- Activities of Daily Living (staff rated **Life Skills Profile*** [Parker et al., 1991])
- Details of current prescribed medication (one item from **Client Service Receipt Inventory*** [Beecham and Knapp, 1999])
- Medication adherence (two items from **Life Skills Profile*; Compliance Scale*** [Heyward et al., 1995])
- Mental health and social functioning (**Health of the Nation Outcome Scale*** [Stein, 1999])
- Engagement in community activities - proforma and **Time Use Diary*** [Jolley et al., 2006]
- Risks - substance misuse (**Clinician Alcohol and Drug Scale*** [Drake et al. 1996]); vulnerability to exploitation (item 9 on **HoNOS*** scoring 3 or 4 plus specific questions to key staff); incidents of self-harm or aggression (HoNOS items 1 and 2 scoring 2 or more plus specific questions to key staff)

- Engagement with services/therapeutic alliance (**Scale to Assess Therapeutic Relationships in Community Mental Health Care** [McGuire-Snieckus et al, 2007])

We estimate the staff interview will take around 45 minutes and the researcher will also spend around 30 minutes reviewing the case notes.

Adaptation to independent living and integration into wider society is complex for people with serious mental health problems. Choosing one primary outcome for a large scale trial does not reflect the real world of recovery where there are multiple social and psychological outcomes to consider, and it ignores the probable correlation between different outcomes and their predictors (Freemantle et al, 2010). Therefore we shall use this opportunity to explore analysis of more than one key outcome in a single multivariate statistical model whilst preserving the distinctness of the outcomes. We already have experience of such analysis in one randomised trial involving people with intellectual disability (Hassiotis et al, 2009) and in another with older people treated for depression (Serfaty et al, 2009). We expect to consider at most three outcomes for joint analysis. Given the small sample size, this analysis will be exploratory.

## QUALITATIVE EVALUATION

We will carry out in-depth qualitative interviews with 10 participants and 10 key staff involved in the referring process (e.g. referrals coordinators, referring clinicians and supported accommodation staff) to assess their experiences of the trial including the process of randomisation, and their views on the usefulness and feasibility of a larger scale trial. Interviews will be recorded, independently transcribed and anonymised. The text data will be entered into a software package (Atlas-ti) to assist management and coding. A coding frame will be developed by one of the researchers with supervision from SP and GL. The main topics included in the interview prompts will be used as the basis for the coding frame which will then be expanded and modified to include further codes as new themes and sub-themes emerge in the course of interviews and analysis. A detailed and comprehensive analysis strategy will be agreed at the early stages of data collection. However, it is not our intention to produce overly interpretative accounts of the experiences of service users and staff, rather to systematically elicit and detail common themes that will inform the feasibility of a larger trial.

A sample of service user and staff transcripts will be randomly selected and re-coded by a second researcher to assess the validity and correlation of coding. Agreement will be considered to have occurred if both coders used the same code(s) for a paragraph of text.

Analysis will be informed by the principles and guidelines for quality in qualitative research (Spencer et al., 2003). A full report detailing the coding and thematic development, alongside a comprehensive list of quotations and exemplars, will be made available.

## DATA MANAGEMENT

Data will be entered onto a purpose designed database by the researchers. Data management will be according to the Barts and the London Pragmatic Clinical Trials

Unit (PCTU) Standard Operating Procedures. Data checking and cleaning will be carried out by the junior statistician in conjunction with the researchers. Cleaned data will be transferred to Stata statistical software for analysis at PCTU. All paper data will be stored in locked filing cabinets and electronic data will be password protected. Once analysis is complete all superfluous paper data will be shredded and appropriate data will be stored in Barts and The London archives for 20 years.

**MASKING OF RESEARCHERS**

Given that the researchers will need to visit the services to collect follow-up data it may not be possible for them to remain masked to participant allocation. However, many of our likely outcomes are objective and independent of potential rater bias. We will explore the feasibility of using a telephone interview to collect follow-up data from service users, conducted by a second researcher who remains blinded to the participant's allocation. This would involve the site researcher visiting the participant at their supported accommodation/home and taking informed consent for the follow-up interview. They would then telephone a second researcher based at the research office who would then complete the interview with the participant.

**LIKELY RATE OF LOSS TO FOLLOW-UP**

It is unlikely that we shall lose many service users to follow-up due to the high support they receive from services. However, many of our outcomes are assessable from case notes and staff rated measures so that if a service user is not contactable we will be able to gather some outcome data. We will seek consent for this at recruitment.

**STATISTICAL ANALYSIS**

We shall follow CONSORT guidelines on the analysis of randomised trials for the presentation of our results (or the CONSORT extension for pilot/feasibility trials if these are published by the time we publish). However, our analysis will be mainly descriptive and will focus on the recruitment rate, acceptability of randomisation to participants and staff, ease of collection of data, characteristics of participants, other baseline and outcome variables, the feasibility of masking outcome assessments, loss to follow-up and any adverse events. We shall provide a descriptive analysis of our principal outcomes and assess the potential for combining them in one multivariate analysis in a main trial. Although we do not expect any statistically significant difference in our outcomes, the confidence intervals of our estimates will assist in calculating power and sample size for a full trial.

**COST EFFECTIVENESS**

Service use in the period before follow-up will be measured using the CSRI (Beecham and Knapp, 1999) and combined with unit costs. The service costs will be derived from expenditure data. Cost-effectiveness of the two types of service will be assessed by combining service costs with the composite outcomes described above. We will also use the SF36 (Ware et al., 1996) and EQ5D (Williams, 1995) to derive QALYs. The use of both is appropriate because there are concerns about using the EQ5D in this population (McCrone et al., 2009). The SF36 and EQ5D will be collected from service users at baseline and 12-month follow-up.

The relationship between EQ5D and SF36 (via the SF6D) QALYs and the other outcome measures will be examined. Uncertainty around the cost-effectiveness

estimate will be assessed using planes and cost-effectiveness acceptability curves and will depend ultimately on which primary outcome(s) is chosen.

**OUTPUTS**

Assessment of feasibility, required sample size and appropriate outcomes for a large scale randomised trial of two supported accommodation models.

**TIMEFRAME**

Month 31-44. Recruitment and baseline data collection
Month 31-40. Qualitative interviews with staff and service users
Month 41-54. Follow-up data gathered 12 months after randomisation
Month 55-60. Data cleaning, analysis and write-up

**FINANCE**

The Quality and Effectiveness of Supported Tenancies for People with Mental Health Problems (QuEST) Project is funded by the National Institute for Health Research Programme Grants Scheme in the amount of £1,642,079. The award will be administered by Camden and Islington NHS Foundation Trust.

**COMPLAINTS**

In the event of a complaint about the conduct of the study, the complaints should be reported immediately to the JRO *research-incidents@ucl.ac.uk* who decide which complaints policy applies and who will be the lead organisation. The NHS complaints policy can only apply where the research subject is recruited through an NHS Trust. In other circumstances the UCL complaints policy will apply.

**INDEMNITY**

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital’s duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

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