EVALUATION OF THE CONNECTING PEOPLE INTERVENTION: A PILOT STUDY

Background
A number of factors including increasing life expectancy, increasing expectation about independence and decreasing institutional care are creating a sustained growth in the need for social care services for adults in England (1, 2, 3). The Government is currently considering the recommendations of the Dilnot Commission on Funding of Care and Support to establish how this increasing need can be met from diminishing public resources. However, it is clear within its vision for a ‘Big Society’ that the Government aims to increase the role of civil society in the provision of public services such as social care (4, 5).

Communities are to be empowered to develop local arrangements for the care of vulnerable and marginalised people, based on the reciprocal principle of providing and receiving services, facilitated by personal budgets (4). Integral to its aim of developing strong communities, the Government is committed to enhancing individual and collective well-being (6, 7). Defined as “a dynamic state in which the individual is able to develop their potential, work productively and creatively, build strong and positive relationships with others, and contribute to their community” (8, p.19), well-being is enhanced when an individual is able to fulfil their personal and social goals and achieve a sense of purpose in society.

Vulnerable adults in need of care services are frequently marginalised in communities and have restricted social networks (9, 10). Some social care workers help people to build relationships and strengthen their connections with their local community (11), but this is afforded a low priority by many (12) in spite of increasing evidence of the importance of social capital for health and well-being (13). To address this, the lead applicant (MW) is currently leading a School for Social Care Research funded study to develop a social capital intervention in accordance with Medical Research Council guidelines (14). The Connecting People study is using ethnographic methods to investigate the potential of social care workers to assist people with psychosis to develop and enhance their social relationships. From his previous work (15), he anticipates that interventions will need to achieve synergy between engaging with wider social structures which constrain opportunities for accessing social capital and enhancing individual capacity for building relationships. Hence, their effectiveness will depend not only on the skills, knowledge and experience of the workers, or the social functioning of the individual concerned, but on having a receptive community that is willing to connect with marginalised and stigmatised people. A similar approach to addressing social exclusion has previously been proposed (16).

Local communities can be important settings for the promotion of well being as they can facilitate social interaction, which in turn supports the development of social networks, social support and social capital, all important determinants of health and well-being (17). Community engagement interventions produce subjective gains in physical and psychological health, self-confidence and social relationships, but can cause stress and drain an individual’s energy levels (18). Initiatives such as voluntary work (19) and time banks (20) promote social interaction in non-stigmatised locations and help marginalised people to enhance their access to social capital. However, the evidence base for community engagement interventions that promote well-being is slim (18).

There is robust evidence that positive and supportive social relationships are associated with well-being (15, 21, 22). Consequently, building connections with people is the first of ‘Five Ways to Well-Being’ (23). The intervention being developed in the Connecting People study will train social care workers to more effectively help the people they work with to enhance and develop their social relationships. The intervention will require an organisational commitment from social care agencies to be fully embedded within their local communities; it will provide accessible and effective training for workers in methods that they can use to help people connect with others and engage with their local communities; and self-help guides for service users. However, evidence of the effectiveness and cost-effectiveness of social care interventions which help people to develop and enhance their social relationships is lacking.

This study will pilot this new intervention in a sufficiently large and diverse sample to provide...
Aims and Objectives
The study will pilot and evaluate the new intervention being developed in the Connecting People study in comparison with other social care approaches to improving social participation and well-being. The diverse nature of the interventions being studied, and the use of three social care user groups, will allow us to answer the research question more fully than if only one were studied. We will also use this study to obtain data about the Connecting People Intervention in preparation for a later randomised controlled trial, if pilot data indicates that it is both effective and cost-effective. In particular, this study will aim to:

- Evaluate the effectiveness and cost-effectiveness of the Connecting People Intervention, other social care interventions in promoting the social participation and well-being of adults with a learning disability or a mental health problem and older adults with a functional mental health problem
- Assess the feasibility and acceptability of the Connecting People Intervention; calculate recruitment and retention rates; and calculate an effect size for the intervention to provide information for a future sample size calculation for a randomised controlled trial.
- Assess how service users experience the interventions being evaluated and their perceptions about how they could be further optimised.
- Evaluate how contextual variations in social care interventions influence outcomes for service users.
- Assess the leadership and workforce implications for social care agencies in implementing the most effective interventions in meeting ‘higher order’ outcomes in routine practice.

Methodology
The study will comprise four modules utilising a range of methodological approaches. The indicative time and duration of each module is given to illustrate their inter-relationship and sequence in the study.

Module 1: Systematic and scoping reviews (Jan 2012–June 2012)
Background: There are no published systematic reviews of social care interventions that produce 'higher order' outcomes such as social participation and well-being. We will conduct a systematic review of these interventions, and a scoping review of social care practice in England, to inform the selection of agencies and interventions for the quasi-experimental study (module 4).

Method: We will use the reviewing method of the Evidence for Policy and Practice Information and Coordinating Centre (EPPI-Centre) that is frequently used by the Social Care Institute for Excellence (SCIE) in its reviews. The EPPI-Centre review method encompasses more diverse types of data than would be included in Cochrane or Campbell systematic reviews and is useful because very few randomised controlled trials have been conducted in this field.

Inclusion/exclusion criteria: The review will have necessarily broad inclusion criteria:
- Population – adults with learning disabilities (aged 18-65), adults with mental health problems (aged 18-65), older adults with a functional mental health problem (aged over 65). Studies will be grouped according to population and reviewed separately.
- Intervention – any social intervention or way of working that is, or could be, used by social care workers will be reviewed. Psychological therapies or medical treatments with no social components will be excluded.
- Comparison intervention – studies using any or no comparison intervention will be included.
- Outcome – studies reporting inter-personal social outcomes such as social participation, community engagement or social network enhancement; or quality of life and well-being. Studies that consider these outcomes qualitatively will also be considered for inclusion.
- Procedures: A researcher will search a diversity of electronic bibliographic databases from relevant disciplines and search online for grey literature; and hand search reference lists and
journals known to members of the research team and advisory group. The researcher will apply the inclusion/exclusion criteria to potentially relevant papers and select papers for the review. A sample of papers on the long-list will be jointly assessed by MW to ensure reliability in application of the inclusion/exclusion criteria.

Papers will be grouped and appraised according to study design. Appropriate critical appraisal checklists will be used to assess methodological quality, trustworthiness, credibility and the importance of findings so that the papers can be presented hierarchically according to their respective contributions to the evidence base. MW will also appraise a small sample of included papers to enhance reliability. Inter-rater reliability will be assessed qualitatively by DM, who will compare the appraisals of the researcher and MW.

**Analysis:** Results will be extracted from papers, collated by intervention, and social care user group, and presented descriptively. We will subject the results to thematic synthesis, which involves coding findings from each study, organising them into themes and then interpreting them to yield ‘analytical’ themes (24). Meta-analyses will be applied to quantitative data if it is sufficiently homogeneous and meaningful to do so.

**Scoping review:** A simultaneous scoping review will be undertaken by the research team and advisory group. Using their expert knowledge of social care in England, they will identify agencies, projects and interventions that appear effective, or demonstrate good practice, in improving individuals’ social participation and well-being, even if there is no research evidence of this. The applicants and steering group members will cascade requests for information through their networks; the mailing list of SSCR; via social media; a project website; and email lists.

A research administrator will collate and organise descriptions of social care practice identified in this scoping review. The research team and advisory group will convene as an expert panel to review the good practice descriptions. We will individually rate each practice description according to likely effectiveness and evidence of good practice. Ratings will be discussed in a meeting and refined using the Delphi consultation method (25) to achieve consensus from the diverse perspectives embodied in the expert panel. The practice descriptions will be synthesised and presented alongside the systematic review.

**Module 2: Adapting the Connecting People Intervention (Jan–Aug 2012)**

**Background:** The Connecting People study is collecting data from social care practice primarily with people experiencing an early episode of psychosis, although its sample includes some people with other health and social care needs. The intervention it is developing is derived from Lin’s social capital theory (26) and modified according to the observations of practice made in the course of the ethnography. An intervention manual will be written which will articulate the underlying theory of change; detail the training that should be delivered to workers and provide clear guidance to workers about the content and delivery of the interventions. The manual for the Connecting People Intervention is being developed by MW, and then refined via a Delphi consultation, from January to July 2012. If funded, this project will additionally produce two separate intervention manuals for use with adults with learning disabilities and older adults in addition to the one for adults with mental health problems. The co-applicants with expertise in learning disabilities (PB) and older adults (PK) will advise and support MS as he develops two fully modified versions that will be piloted within this project.

**Method:** We will use a parallel Delphi consultation process to the one planned for the Connecting People study to refine the modified versions, ensure they are feasible in practice and remain faithful to social capital theory. This method will allow us to achieve consensus from a diverse range of perspectives.

**Procedures:** We will recruit two reference groups of a minimum of 30 participants in each for the Delphi consultation of the two adapted intervention manuals, with expertise in adults with learning disabilities and older adults with functional mental health problems respectively, comprising practitioners, users, carers and social care researchers. A core reference group of international social work, attachment theory and social capital experts recruited for the Delphi consultation in the Connecting People study will also be drawn upon.

The reference groups will be recruited from the applicants’ professional networks which
extend across numerous health, social care and third sector agencies in England. We will use a maximum variation sampling strategy to ensure that heterogeneous perspectives on the intervention manuals can be included in the Delphi consultation. They will include a wide variety of experts, including those with lived experience and self-advocates from user-led organisations. Reference group members will be asked to comment critically on the validity of the intervention for their respective user groups. Whilst we will not expect them to pilot it within their agencies, we will invite people to participate in these reference groups who have relevant expertise to comment on the applicability of the intervention in their setting. The robust Delphi Consultations will allow us to refine the intervention manuals and make them fit for purpose prior to piloting.

The Delphi consultation will be conducted via email. Reference group members without access to email will participate via postal questionnaires. Participants will be sent a draft of the intervention manual and a structured self-complete questionnaire for them to provide us with their feedback. This questionnaire will comprise standardised ratings on the fidelity of the intervention to social capital theory; adequacy, clarity and comprehensiveness of the intervention guidelines; and feasibility and acceptability of interventions in practice. We will additionally ask for brief qualitative responses to these items to inform the refinement of the intervention.

Mean ratings on the standardised measures will be calculated to inform the revision of the intervention, supported by the qualitative feedback where appropriate. We will undertake a second round of consultation using the same method and feedback questionnaire after the intervention has been amended. The iterative consultation will provide an opportunity for members of the reference group to re-evaluate their opinions in the light of the average ratings of the group. The Delphi consultations and refinement of the two additional manuals will be conducted in parallel with that in the Connecting People study to maximise efficiencies and ensure the shared development of the interventions.

**Module 3: Development and validation of fidelity scale for the Connecting People Intervention (Jan 2012–March 2014)**

**Background:** Fidelity scales measure the extent to which a standardised intervention is being delivered and are particularly important in intervention research (27). As we aim to pilot the Connecting People Intervention in multiple sites (module 4), and evaluate it in a later randomised controlled trial, a fidelity scale is essential.

**Method:** We will develop items for the Connecting People Intervention Fidelity Scale (CPIFS) alongside the development of intervention manuals in module 2. The CPIFS will include items to measure organisational structures, workers’ practice and service user perceptions of practice in respect of the Connecting People Intervention. The measure will comprise an assessment of the organisation’s engagement with the local communities of the social care service users which it serves; questions for workers and their supervisors about delivering the intervention; and questions for service users about receiving the intervention. The measure will include both expert appraisal of intervention fidelity and self-report. The item pool will be developed and refined by the research team and the CPIFS will also be included in the Delphi consultation in module 2 to refine it further. The CPIFS will be amended accordingly and piloted in module 4. It will be administered to all participants alongside other measures to minimise respondent burden and maximise efficiencies.

**Analysis:** The discriminant validity of the CPIFS will be assessed by comparing its results from the agencies delivering the Connecting People Intervention in comparison with the agencies which are not. Its predictive validity will be assessed by comparing the outcomes of agencies scoring high on the measure with those scoring low.

**Module 4: Quasi-experimental study (June 2012 – March 2014)**

**Background:** Randomised controlled trials (RCTs) are the ‘gold standard’ method of intervention evaluation, as randomisation minimises selection bias. However, the efficacy of the Connecting People Intervention is unproven and there is no critical equipoise to justify randomisation. It first requires piloting in diverse settings to allow us to assess its feasibility and acceptability; calculate recruitment and retention rates; and an effect size for the intervention to provide
Design: We will pilot it in a quasi-experimental study in which the Connecting People Intervention will be compared with other services and interventions designed to support social participation and well-being. The study will be powered to ensure that conclusions can be drawn about its likely effectiveness and cost-effectiveness.

Setting: We will recruit 12 social care providers to the study with 6 providing the new intervention and 6 providing existing services; 6 in the north of England (within reach of Preston) and 6 in the south of England (within reach of London); 4 each working with adults with learning disabilities, adults with mental health problems and older adults with functional mental health problems. The distribution of agencies is illustrated in the matrix below:

<table>
<thead>
<tr>
<th></th>
<th>Connecting People Intervention</th>
<th>Comparison Interventions</th>
</tr>
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<tbody>
<tr>
<td>Adults with learning disabilities</td>
<td>2 Agencies: (1-North, 1-South)</td>
<td>2 Agencies: (1-North, 1-South)</td>
</tr>
<tr>
<td>Adults with mental health problems</td>
<td>2 Agencies: (1-North, 1-South)</td>
<td>2 Agencies: (1-North, 1-South)</td>
</tr>
<tr>
<td>Older adults</td>
<td>2 Agencies: (1-North, 1-South)</td>
<td>2 Agencies: (1-North, 1-South)</td>
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The Connecting People Intervention will be provided by some of the agencies involved in the Connecting People study and others known to the research team and advisory group. Agencies will be selected on the basis of their ability to readily adapt to the requirements of the intervention, to support their workers in delivering it and to support the recruitment of participants to this study. If we are able to recruit one large agency for each cell of the above table, which will meet our study recruitment targets, it may not be necessary to recruit a second one. However, we will ensure an equal representation of agencies from the north and south of England as much as possible. Agencies will be recruited during module 1. MW and others in the research team as appropriate will provide the Connecting People Intervention training and advise agencies on implementing it according to the intervention manuals.

The comparison interventions will be selected during module 1 as likely to be effective in enhancing people’s social participation and well-being. They will be sufficiently heterogeneous to allow us to evaluate multiple approaches to achieving ‘higher order’ outcomes, but sufficiently homogeneous to facilitate a meaningful comparison. The inclusion of multiple agencies across three user groups will make the study more naturalistic and potentially more generalisable. From our experience in the Connecting People study, many social care agencies in the voluntary sector enhancing people’s social participation and well-being are keen to evaluate their practice as they lack the resources to do so themselves, which will facilitate the recruitment of agencies in this study.

Sample: Participants for the study will be recruited from new referrals to the agencies that meet their eligibility criteria and accept a service. New referrals are selected to allow us to measure the full effect of the interventions which may not be achieved by selecting existing service recipients. We accept that different referral criteria and agency practices will make the sample heterogeneous, but this will allow us to evaluate the interventions in people with different social care needs. People without capacity to consent will be excluded, though people with mild to moderate learning disabilities will be included as we will use different information sheets and the support of carers to obtain informed consent.

We will recruit 40 people from each cell of the matrix above (20 per agency if it is not possible to recruit all these from one agency alone) to participate in the evaluation. Allowing for a 25% loss-to-follow-up, this will provide a sufficient sample to pilot the intervention in each user group (28).

Sample recruitment from the agencies in the comparison group will begin in June 2012, whilst recruitment of those receiving the Connecting People Intervention will begin in Sept 2012 whilst the intervention is being initiated in the selected agencies. We will aim to complete recruitment in Jan 2013 to allow us to complete a 12-month follow-up by Jan 2014, as measurable changes in ‘higher order’ outcomes such as social participation can take this long to become evident (15). Recruiting 240 participants in 8 months will be a challenge, but this will be feasible if we
select agencies that have a high rate of new referrals and are willing to help facilitate recruitment to the study. We will recruit additional agencies to compensate for under-recruiting ones if the shortfall cannot be made up from others.

**Procedures:** All new referrals to participating agencies will be provided with study information sheets by the agencies. The contact details of those who express an interest in participating will be forwarded to the researchers who will obtain their informed consent to take part. Research interviews will be conducted at baseline and 12 months.

Participants in the Connecting People Intervention group will receive the normal service of the agency supporting them supplemented by the Connecting People Intervention. Workers will be trained in network mapping and other techniques to support service users in identifying opportunities for enhanced social engagement. They will be supported to develop and maintain social relationships with family, friends and members of the local community as appropriate to their needs and wishes. Participants in the comparison group will receive the normal service of the agency which will comprise a variety of interventions which also aim to support social participation and well-being. Participants are free to withdraw from the intervention or study at any point. However, if participants withdraw from the intervention but not the study, they will continue to be followed up unless they withdraw from this also.

**Measures:** A socio-demographic questionnaire will be administered at baseline. Potential confounding variables will also be measured, including attachment style (29) and life events during follow-up (30). Valid and reliable outcome measures have been selected which are sensitive to change and suitable for use in multiple user groups, and will be administered at each data collection point. Social participation will be measured by SCOPE (31), which captures both objective and subjective dimensions of social inclusion; well-being will be measured by the WEMWBS (32); and access to social capital will be measured by the RG-UK (33). We will also administer the service user questions of the CPIFS (module 3) at 12 month follow-up.

**Analysis:** Using 12-month follow-up data, we will construct a longitudinal random effects model in Stata for each outcome measure. This method accounts for repeated measures and controls for baseline values and confounding variables. Intervention type and user group will also be entered into the model to evaluate their independent effect on outcomes. Additionally, we will calculate recruitment and retention rates and an effect size for the intervention to provide information for a future sample size calculation for an RCT.

**Economic evaluation:** The cost of training workers to deliver the interventions will be calculated by collecting information on training time and personnel involved, plus overhead costs. These costs will be apportioned over all participants in the study who receive the intervention. Other costs will be calculated by collecting service use data at baseline and 12-month follow-up using the Client Service Receipt Inventory (CSRI) (34) and combining this information with appropriate unit cost information (35). Services will include health and social care and also care from family members in specific areas (personal care, child care, help in the home, help outside the home). Informal care will be costed using the cost of a homecare worker as a proxy value. In sensitivity analyses minimum and average wage rates will be used to cost lost carer work time and a proportion of this (25-100%) to cost lost carer leisure time. (The CSRI will ask what carers would have been doing if not providing care.)

Quality adjusted life years (QALYs) will be estimated and used in the economic evaluation. NICE recommends the use of the EQ-5D (36) and this will be used here. In subsequent analyses we will use the ICECAP-A (37) which focuses more on capability and well-being rather than purely health. Utility values are available for this measure but these do not allow QALYs to be generated.

**Analysis:** If costs are higher and outcome better for the Connecting People Intervention or comparison group then we will produce incremental cost-effectiveness ratios (difference in costs divided by difference in QALYs) to show the extra cost per extra QALY gained. Uncertainty around cost-effectiveness will be investigated by obtaining 1000 cost-outcome pairs using bootstrapping and plotting these on a cost-effectiveness plane. Cost-effectiveness will further be assessed using the net benefit approach where the outcome (QALYs gained) is combined with values within a specified range (here £0 to £100,000 in £10,000 increments so as to
include the NICE threshold) with service costs then subtracted. This approach allows multivariate analysis of cost-effectiveness to allow for comparisons between the different groups whilst controlling for differences in demographic and clinical/social characteristics. By doing this for each of the values in the above range, and using bootstrapping, we will produce cost-effectiveness acceptability curves to show the probability that the intervention is cost-effective for different QALY values. These analyses will be repeated using utility scores generated from the ICECAP-A. Threshold values for changes in these scores are not available and we will use a range such that the value at which the Connecting People Intervention or the control condition has a 50% and 75% likelihood of being the most cost-effective option can be identified. (We recognise that these points are themselves arbitrary.)

Process evaluation: Participant follow-up interviews at 12 months will include a small qualitative component which will focus on the participant’s experience of the intervention; their perceptions of its benefits for them; and how it might be improved. We will discuss their perceptions of their social participation and well-being; any changes they may have experienced since the start of the study; and possible reasons for this.

At 12 months following the start of participant recruitment in each agency we will interview in depth one supervisor and two social care workers from each agency about the interventions they have been delivering. We will administer the CPIFS (module 3) and discuss workers’ experience of the effectiveness of their practice in improving individuals’ social participation and well-being. In the agencies delivering the Connecting People Intervention we will enquire about workers’ experience of the training; agency and supervisor support for the interventions; the intervention manual and the process of implementing it. We will also use these interviews to assess the leadership and workforce implications of the interventions being evaluated.

Qualitative components of follow-up interviews and the in depth interviews will be audio-recorded and transcribed in full. Data will be analysed as an iterative process throughout data collection using the constant comparative method in grounded theory (38). This will involve a detailed reading and re-reading of the transcripts to identify initial themes, which will be refined through comparisons of text subsumed under each thematic category. Furthering questioning of the data and comparison of the categories with one another will help us to develop more abstract thematic categories. Analysis will be aided as appropriate with use of NVivo to assist tasks of coding, retrieving and comparing data.

References
24. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. BMC Medical Research Methodology. 2008; 8(45).