

EVALUATION OF THE CONNECTING PEOPLE INTERVENTION: A PILOT STUDY

Study protocol

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 (1-3). 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), 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 evidence about its effectiveness and cost-effectiveness across three social care user groups – adults with a learning disability, adults with a mental health problem and older adults with a mental health problem.

Aims and Objectives

The study will pilot and evaluate the new intervention being developed in the Connecting People study which aims to improve social participation and well-being. In particular, this study will aim to:

- Evaluate the effectiveness and cost-effectiveness of the Connecting People Intervention, 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

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 (CPI) 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 information for a future sample size calculation for an RCT (14).

Design: We will pilot it in a quasi-experimental study in which the CPI will be implemented in a diverse range of teams or agencies which promote 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 – 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:

	<i>Connecting People</i> Intervention
Adults with learning disabilities	4 Agencies: (2-North, 2-South)
Adults with mental health problems	4 Agencies: (2-North, 2-South)
Older adults with mental health problems	4 Agencies: (2-North, 2-South)

The CPI 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 already providing interventions similar to the CPI; their ability to readily adapt to the requirements of the intervention; their ability and readiness to support their workers in delivering it; and their ability to support the recruitment of participants to this study. If we are able to recruit one or two large agencies or teams for each cell of the above table, which will meet our study recruitment targets, it may not be necessary to recruit all four. 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 a pre-study phase (January – March 2012). MW and others in the research team as appropriate will provide the CPI training and advise agencies on implementing it according to the intervention manuals.

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 80 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 (24).

Sample recruitment will begin in June 2012 when teams and agencies will start to receive training in CPI. Training will be completed by Sept 2012, by which time participant recruitment in all the agencies will be underway. 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 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 (25) and life events during follow-up (26). 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 (27), which captures both objective and subjective dimensions of social inclusion; well-being will be measured by the WEMWBS (28); and access to social capital will be measured by the RG-UK (29). We will also administer the service user questions of the CPI Fidelity Scale (CPIFS).

Analysis: We will test the hypothesis that higher fidelity to the CPI will be associated with improved outcomes. We will use analysis of covariance to evaluate the association of the CPIFS with each outcome measure, whilst controlling for baseline values and potential confounding variables. We will also control for the effect of clustering by agency and user group to evaluate

the independent effect of fidelity to CPI 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. All analysis will be conducted using Stata.

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. Other costs will be calculated by collecting service use data at baseline and 12-month follow-up using the Client Service Receipt Inventory (CSRI) (30) and combining this information with appropriate unit cost information (31). 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 (32) and this will be used here. In subsequent analyses we will use the ICECAP-A (33) 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: Cost-effectiveness analyses conventionally compare 2 or more groups. In this study we propose to dichotomise the CPIFS at the median for the purpose of creating 2 groups. If costs are higher and outcomes better for one of the groups 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 two 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 high-fidelity services are 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.) Finally, we will analyse variation in net benefits as described above but this time keeping CPIFS as a continuous measure. This will allow us to estimate the impact on net benefit of a one-unit improvement in fidelity.

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 and discuss workers' experience of the effectiveness of their practice in improving individuals' social participation and well-being. We will also 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 (34). 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. Further 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.

Timetable

Pre-study (Dec 2011-June 2012): obtain ethical approvals; convene advisory group; recruit research team; conduct scoping & systematic literature reviews to help identify agencies for intervention and comparison group; recruit agencies; obtain research governance approval.

Recruitment phase (June 2012-Jan 2013): Train workers for Connecting People Intervention (June-Sept 2012); recruit cohort in Connecting People Intervention group (July 2012-Jan 2013)

Follow-up phase (June 2013 – Jan 2014): collect 12 month follow-up and process evaluation data; data analysis (Feb-Mar 2014).

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