

Improving Care for People with Dementia:

Development and Initial Feasibility Study for Evaluation of Life Story Work in Dementia Care

Research Protocol

Background

Listening to people with dementia and understanding that they have rich and varied histories is essential to good care¹. 'Life story work' is used increasingly for this and involves gathering information and artefacts about the person, their history and interests, and producing a picture book or other tangible output – the 'life story' - including storyboards and multi-media resources². Life story work has been used in health and social care settings for nearly three decades, with children³, people with learning disabilities⁴ and older people⁵. Since the 1990s, there has been growing interest in its potential to deliver person-centred care for people with dementia^{6,7}.

The approach is distinct from reminiscence and 'biographical work' in dementia care, because it emphasises using the life story in day-to-day care to improve communication, relationships and understanding of the individual's past life, and in its orientation to the future. The NICE/SCIE guideline on supporting people with dementia and their carers⁸ presents a vivid example of a situation in which a life story might improve the quality of care, and thereby outcomes, for a person with dementia:

By learning about each person with dementia as an individual, with his or her own history and background, care and support can be designed to be more appropriate to individual needs. If, for example, it is known that a man with dementia was once a prisoner of war, it can be understood why he becomes very distressed when admitted to a locked ward ... Without this background knowledge and understanding, the man who rattles the door may be labelled a 'wanderer' because he tries to escape and cowers when approached ...

(p.71)

Life stories, as tangible products, are owned and held by people with dementia and can travel with them to smooth transition to other settings, for example into acute medical care, or from home to long-term care. This makes them distinct from biographical 'work' in care settings⁹ or the simple logging of life history details in care records.

Two systematic reviews have explored life story work in dementia care and both suggest the approach has considerable potential. The first¹⁰ reviewed life story work with a range of user groups and reviewed four qualitative studies focused specifically on dementia. These studies suggested that life stories can help staff to understand the person they are caring for in the context of their past, which in turn can help to explain their present behaviours. Staff valued life story books as care planning and assessment resources, but there was little reporting of patients' and carers' views. The review's authors noted an absence of attempts to present conflicting evidence about the value of life stories in practice. The second review identified 28 studies of life story work with people with dementia in institutional settings¹¹. All interventions contained some features important for achieving an enhanced sense of identity among residents. However, the study focus tended to be the impact of the life story reminiscence process, generally conducted by researchers or therapists for limited periods, while the routine daily use of life stories was seldom included. The authors concluded that there is still much to learn about how best to deliver this approach to people with dementia and that more attention should be paid to developing a sound theoretical framework.

Subsequent studies suggest that life stories help staff to see clients with dementia as individuals, help family carers to uphold relatives' personhood, and enable those with dementia to be heard and recognised as people with unique stories. However, these studies have been very small in scale^{12,13} or remained unpublished¹⁴.

The use of life histories (*sic*) has been advocated in the Department of Health Dementia Commissioning Pack¹⁵ and this in turn refers to a CSCI report which commended the use of life histories in care planning¹⁶. However, life story work for people with dementia is under-researched, with little evidence about the most cost-effective ways to implement it in different settings or with different user groups. To date, there have been no large-scale, methodologically rigorous studies of the impact of life story work on outcomes for people with dementia, carers and staff, or any attempt to establish its costs. More basically, unlike reminiscence therapy¹⁷, the mechanisms that might make life story work effective, or the contexts in which these might apply, have not been articulated; there is thus no developed theory of change that underpins its use. Finally, while descriptive accounts and practice-based knowledge show life story work being used in different ways in different dementia

care settings, we have no systematic knowledge about who is using it, where, how, with what effect and at what financial cost.

With current moves towards embedding life story work in dementia care, robust evaluation of the technique, its outcomes and costs, and how it can best be applied is urgently needed. As a complex intervention, however, this must be preceded by development and feasibility/pilot stage research, as recommended in the most recent MRC guidance¹⁸.

The need for research

Health need

There is a need to understand how life story work might improve interactions and relationships between staff, carers and people with dementia in a range of health and long-term care settings; affect service users' and carers' quality of life and other individual outcomes; and reduce the use of anti-psychotic drugs for behavioural 'problems'. There is also a need to establish the likely costs and benefits of implementing life story work more widely in health and long-term care settings.

Expressed need

The Department of Health has recently outlined improved quality of care in general hospitals, living well with dementia in care homes, and reduced use of anti-psychotic medication as priority objectives for dementia¹⁹. Quality outcomes for people with dementia in NICE Quality Standards²⁰ focus on improving health outcomes through improving care processes, and two quality statements emphasise the importance of understanding people with dementia via their life stories and biographies.

Sustained interest and intent

Dementia is a major and growing health problem across the world. When cure is unlikely, providing good quality and cost-effective care, over what is often a long period of need is, and will remain, a major challenge for health and other care providers.

Capacity to generate new knowledge

Despite its use in dementia care settings in the NHS and elsewhere, the outcomes of life story work for people with dementia, their carers, and staff, its costs, and impact on care quality remain unevaluated. This project will provide theoretical underpinnings for life story work, good practice guidance in its use, establish where

and how it is used in health and other care settings in England, outline its possible costs and benefits in such settings, and establish the feasibility of formal evaluation.

Generalisable findings and prospects for change

The project will generate a robust theory of change and a good practice framework to underpin growing use of life story work in dementia care for the NHS management community to use. Elucidating potential outcomes, impact on care quality, and the costs of life story work can also inform commissioning decisions about where and how best to use life story work. Future formal evaluation of life story work, building on the work proposed here, would provide robust, generalisable evidence of effectiveness and costs.

Building on existing work

The research is part of a portfolio of research at York dealing with care for people with severe and complex needs, including dementia, and also that at York and by co-applicants on developing and applying methods for involving people previously considered 'hard to reach' in research. It will add to the growing stream of projects across the HS&DR programmes that explore how best to deliver high quality care to older people.

Research aims and objectives

Aim

- To carry out the development and initial feasibility stages of evaluation of a complex intervention – life story work – for people with dementia.

Objectives

- Develop a theoretical model of life story work (including its potential outcomes) and establish core elements of good practice in using and applying the approach.
- Benchmark the current use of life story work in dementia services in England against good practice.
- Scope the potential effects and costs of using life story work in specialist inpatient and long-term care settings.
- Explore the feasibility of formal evaluation of life story work in health and long-term care settings.
- Disseminate findings to providers, planners, commissioners and users of dementia services.

Research questions

- How might life story work improve outcomes for people with dementia, carers, staff and wider health and social care systems?
- How cost-effective could this be?
- Is formal evaluation of life story work feasible?

Design and methods

Medical Research Council guidance points to the special challenges that evaluation of complex interventions poses for evaluators¹⁸. The guidance suggests that before formal evaluation of effectiveness and costs commences, an understanding of the existing evidence base, a developed theory of change, process and outcome modelling, and a clear understanding of the feasibility of formal evaluation must be in place. These elements are not yet in place for life story work. This project thus focuses on the development and initial feasibility work required before full evaluation, in two main stages: 1) reviewing the evidence base and identifying and developing theory and components of good practice; 2) data collection to support modelling of

processes and outcomes and judgement about the feasibility of full evaluation. A mixed methods approach will be used throughout. Table 1 sets out how each project objective will be met by the project methods.

Objective	Methods
1 Develop a theoretical model of Life Story work, including its potential outcomes, and establish core elements of good practice in using and applying the approach.	A systematic review of literature (1A) published since 1985 on life story work with people with dementia to identify reported outcomes and their sizes, underlying theories of change, and any reported elements of good practice in creating and using Life Stories. A qualitative study (1B) using focus groups with people with early stage dementia, carers and professionals, who have experience of life story work to ascertain what outcomes are experienced or expected, for whom, under what circumstances, and by which causal routes; as well as participants' views about core elements of good practice in life story work.
2 Benchmark the current use of Life Story work in dementia services in England against good practice.	A survey of health and social care providers of dementia services (2A), and of informal carers (2B) to establish how life story work is used in different care settings. Good practice elements identified in stage 1 will influence the survey content, enabling us to benchmark use against good practice.
3 Scope the potential effects and costs of using Life Story work in specialist inpatient and long-term care settings.	Two small scale feasibility studies (2C) - one with a stepped wedge design in care homes, the other a pre-test post-test design in an NHS assessment unit – to examine the potential size of outcomes from and costs of using life story work in these settings. Relevant resource inputs will be identified, measured, and then valued using local or national unit costs to establish the costs of life story work relative to other approaches. Using these preliminary data, and assuming that we have observed any effects, we will create a probability tree for effectiveness of life story work in relation to outcomes and then a Markov model of effectiveness and cost-effectiveness of life story work (2D) This will help to assess whether future, formal evaluation of life story work would be worthwhile.
4 Explore the feasibility of formal evaluation of Life Story work in health and long-term care settings.	In addition to producing data on potential costs and outcomes of life story work, these small-scale studies (2C) will provide valuable learning on the practical feasibility of formal evaluation of life story work in different settings and for two different designs.
5 Disseminate findings to providers, planners, commissioners and users of dementia services.	A short film, designed and produced with the help of people with dementia and their carers will be available to the NHS and other dementia care providers and the public via SPRU and partner organisations' websites and shown at practice-oriented conferences. A four page summary setting out findings, including the model of good practice, will be distributed to all health service providers and commissioners, other dementia care providers, and to relevant third sector organisations and members of the public, and available on the SPRU website and partners' websites.

Stage 1: Reviewing the evidence base and identifying and developing theory

A review of the evidence base and focus groups with people with dementia, their carers and professionals, will be used to develop a theoretical model of life story work, including its potential outcomes, and establish core elements of good practice in using and applying the approach (**objective 1**).

Methods

1.a The review

A systematic review of the existing literature on life story work with people with dementia will identify published empirical studies and theoretical accounts of life story work with people with dementia in all care settings. The review questions will be:

- What outcomes and of what size have been reported for life story work?
- What underlying theories of change for life story work are articulated in the literature?
- What elements of good practice in creating and using life stories are reported in the literature?

Centre for Reviews and Dissemination guidelines²¹ will be followed and we will build on our existing expertise in systematic reviews of complex interventions^{22,23}.

Searching and key word strategies: A simple search carried out in September 2011, using only two terms – *life stor** and *dementia* - searching in Medline, Embase, PsycINFO, and Social Policy and Practice from 1974 onwards, generated 155 publications after electronic duplication, a fifth of which appeared relevant, and none of which was published before 1991. This indicates that our proposed work is feasible and that we can restrict searches to 1985 onwards.

The main electronic databases searched will be MEDLINE, EMBASE, CINAHL, PsycINFO, Social Policy and Practice, SSA, and Social Care Online. We will also search relevant websites for material generated by user-led or voluntary sector enquiry, contact key authors and known experts and hand search reference lists and do forward citation searches on included papers to identify other relevant studies. We will develop full keyword strategies at the beginning of the project, but will include, at least, terms for life story work and its equivalents, and terms for the dementias and their equivalents, alongside study and date filters.

Review strategy: As with most reviews of complex interventions, it is good practice to finesse the inclusion and exclusion criteria for selection for relevance after the first phase of searching²⁴. However, we have developed some initial inclusion and exclusion criteria based on our existing knowledge of this literature.

These are:

- **Inclusion:** any published account of life story work or life stories that is also about one of the dementias and refers to outcomes; any care setting, including own home; any country (UK and non-UK); any empirical study types; any theoretical accounts, including guidance and training documents.
- **Exclusion:** Opinion pieces, letters; published before 1985; not English language.

GP and KG will first screen titles and abstracts for relevance, using the initial inclusion and exclusion criteria, working jointly on 25 records and discussing our decision-making to ensure consistency. We will then decide whether the selection criteria need further adjustment. We will work separately on subsequent records but meet to make final screening decisions.

We will obtain full copies of all material identified as potentially relevant and make decisions about inclusion for review using an algorithm based on our final inclusion and exclusion criteria.

The focus of data extraction will be on outcomes that authors report as arising, actually or potentially, from life story work, for whom these outcomes arise, explicit or implicit theoretical assumptions about causation, and any data on changes in outcomes. To give an example, the results of one life story project¹⁶ have been described thus:

The group that participated in a dyadic life review (caregiver and care receiver) seemed to gain most from the intervention, particularly in their assessment of the care receiver's problem behaviours. Possibly... because they were enjoying the process simultaneously and were sharing an event again.

(p.171)

Here we would record that the carers' assessment of the care receiver's problem behaviours improved (carer outcome) because the dyadic life story process (type of intervention) was shared (implicit causal link) and was enjoyed (implicit causal link). We will also extract details of the type of life story work described, participants, the care setting, study design and any data or discussion related to good practice in

creating and using life stories. In the latter case, and using the same example as above, we would here record the implicit 'good practice' that creating a life story work is better when it is a shared experience.

Both reviewers will extract data from the first 10 papers included, then discuss their decisions and deal with any apparent inconsistencies. Subsequently, we will divide the papers between us for extraction and then check each other's accuracy. We will use Joanna Briggs Institute systematic review software – SUMARI V.5 – for all relevant parts of the review, choosing it for its particular strengths in supporting review and synthesis of qualitative material. We will use the critical appraisal module of the qualitative element (QARI) to assess the quality of included publications.

We will undertake a narrative synthesis²⁵ of the extracted material, using a 'realist' approach²⁶ – establishing what type and size of outcomes are reported, for whom, under what circumstances (including good practice components), and by which (implicit or explicit) causal routes. We will synthesise evidence by the type of life story work used and the characteristics of participants and care setting. Emerging findings will be discussed with co-applicants throughout.

1.b Qualitative study

A qualitative study, using focus groups with people with early stage dementia, carers and professionals, who have experience of life story work will be organised and facilitated by Innovations in Dementia, Uniting Carers and the Life Story Network, and led by KG. There will be three groups for each type of participant, each involving five to ten people. Topics covered in all groups will be: what outcomes are experienced or expected, for whom, under what circumstances, and by which causal routes; and participants' views about core elements of good practice in life story work. Topic guides for the three different types of participant will be developed between the researchers and co-applicants and discussed with our specialist advisor and advisory groups.

Focus groups with people with early stage dementia

The views of people with dementia are usually excluded from both intervention research and that attempting to find appropriate outcome measures for this group²⁷. Yet, there is growing evidence that people with dementia are both willing²⁸ and able²⁹ to take part in research. Given our focus on identifying outcomes and good practice in the use of life story work, our work would be incomplete without the views of people with dementia. Three of the nine focus groups will thus be with people with early stage dementia who have experienced life story work, facilitated jointly by KG and Innovations in Dementia.

Group discussions are a valuable research tool with people with mild to moderate dementia, particularly where there is a clearly defined focus for discussion²⁷. People with moderate dementia are able to share feelings and follow a theme in a group setting³⁰. Group discussion has advantages over individual interviews for people with dementia, including reduced pressure to respond to every question, increased access to memories outside the current context, and mutual support³¹. Nevertheless, group work with people with dementia requires skilful facilitation³²; the focus groups will therefore be supported by Innovations in Dementia, who have a proven track record in this field^{33,34}. They will approach groups they already work with and obtain informed consent to participation. The focus groups will take place in settings known to the participants, where they feel comfortable.

Focus groups with carers of people with dementia

Life story work with people with dementia may have benefits for caregivers and the relationships with the people they care for⁹. Further, carers often play an important role in supporting people with dementia to construct their life stories. Three of the nine focus group sessions will thus be with carers of people with dementia who have experienced life story work, jointly facilitated by Kate Gridley and Uniting Carers. Uniting Carers will approach existing groups of carers of people with all stages of dementia and obtain informed consent. The groups will take place in settings known to participants.

Focus groups with professionals

The remaining three focus groups will be with professionals who have used life story work with people with dementia – from both health and social care settings, including long-stay care. The Life Story Network will identify potential participants and invite them to York to participate. As well as the topics that will be addressed with all groups of participants (see above) professionals will also be asked about drivers of resource use in dementia care settings and what changes, if any, they would expect to see in these if life story work is carried out. This material will be used specifically to inform data collection in stage 2.

Analysis

All the focus groups will be audio-recorded, with participants' permission. They will be transcribed and analysed thematically, to produce a realist account²⁶ of what works, for whom, and in what circumstances, from the perspectives of people with dementia, carers and professionals. A summary of their views on best practice will also be created.

Stage 2: Modelling processes and outcomes

This stage of the project will draw on the findings of stage 1 to identify outcomes and good practice, collect quantitative and qualitative data about life story work implementation, its outcomes, and its costs, model its processes, costs and outcomes, and establish the feasibility of full formal evaluation.

Methods

2.a Survey of providers

A survey of health and social care providers for people with dementia to benchmark the current use of life story work in dementia services in England against good practice (**objective 2**). An on-line survey of health and social care providers of dementia services will establish how life story work is used in different care settings. Good practice elements identified in stage 1 will influence the survey content, enabling us also to benchmark use against good practice.

Sample

We will target significant parts of the care pathway to make an initial judgement about if and how life story work is used across it. Five categories of services - memory clinics, in-patient dementia assessment services, community dementia support services, and generic and specialist long-term care homes - will be the sampling frame, identified through existing directories of English services. Proportional sampling within categories will generate target groups of 100 services in each (500 in total). Initial contact will provide sample members with information about the project, secure their participation and identify the person best placed to complete the survey. Co-applicants will facilitate access to these providers, advertise the survey through their networks, and encourage participation. We anticipate a 70 per cent response rate (n=350) based on previous experience of rigorous follow-up in surveys. This will allow us to estimate proportions to within +/-10 per cent (95 per cent level of confidence).

Survey development and administration: Learning from Stage 1 and expert advice from co-applicants and advisory groups will influence the content and design of the survey. It will cover at least: types of care settings; numbers and proportions of current service users with life stories; types of service users most likely to have life stories; settings where life story work is used; individuals involved in life story work; type of tangible outputs of life story work; and good practice components in use.

A preliminary paper-based survey will be pre-piloted with members of our advisory groups and a small number of service providers, to ensure face validity and comprehensibility. It will then be converted into an online form and piloted with a 1-

in-10 sub-sample of providers. Once finalised, we will deliver the survey to the whole sample for completion on-line. Non-response will be followed-up with two email reminders and a final letter.

2.b Survey of carers of people with dementia

A survey of carers of people with dementia will focus on who has a life story, how it is used and in which settings or circumstances (e.g. in interactions between the carer and person with dementia, in day service settings, in interactions with health or social care professionals etc.), how it was produced, by whom and whether this followed good practice (**objective 2**).

Sample

Uniting Carers will identify and make initial contact with a group of around 400 carers. They will forward information about the project and a consent form and secure participation. We will then post the survey or provide on-line access, depending on carers' choice. Based on previous experience, Uniting Carers would expect between 30-40 per cent of carers to complete the survey (n=120-160). This will allow us to estimate proportions to within +/-7 per cent (95 per cent confidence level).

Survey development and administration

The content and design of the survey will be developed and tested in a similar way to that for service providers. Having a paper-based and an online version will allow carers to choose which format best suits their needs. Pre-piloting and piloting will follow the same format as for service providers, but piloting will test both modes of administration. Non-response will be followed up with one email or one letter reminder, as appropriate.

Analysis

Analysis of both surveys will be predominantly descriptive, using percentages and means (sd) or medians (range) and 95 per cent confidence intervals, as appropriate. Bi-variate analysis will explore differences between those who do and do not use life story work or have a life story, and identify who reports using or experiencing which components of good practice, using chi-squared tests for categorical data and t-tests/ANOVA for continuous data. All data will be imported into SPSS (v19) for analysis.

2.c Scope the potential effects and costs of using life story work in specialist inpatient and long-term care settings (*objective 3*) and explore the feasibility of formal evaluation (*objective 4*).

Exploring feasibility

Medical Research Council guidance confirms that assessment of feasibility and piloting of methods is vital preparatory work in developing and evaluating complex interventions. Piloting will enable us to estimate the likely rates of recruitment and retention of participants in a full evaluation, which is particularly important in research with people with dementia where deteriorating health and mental capacity could hamper recruitment and lead to drop out. It will also allow us to identify any practical barriers to implementing and evaluating life story work using different designs, and any problems with delivering the intervention in new settings.

The involvement of specialist organisations like Innovations in Dementia could help to make the evaluation process more dementia friendly, and piloting the evaluation will allow us to explore this possibility. In order to assess how acceptable patients, carers and staff find the intervention, its implementation and the processes involved in evaluating its outcomes, we will gather in-depth, qualitative information from carers, staff and, if possible, people with dementia in both care home and NHS assessment unit settings. Constraints on the care staff and managers who work with participants may also affect recruitment and retention, as well as success in measuring outcomes³⁵ and it is therefore important to ensure that data collection processes are as straightforward as possible³⁶.

Outcomes to be measured and approaches to data collection identified in stage 1 of the project will therefore be tested in this pilot phase for appropriateness and usability, as well as sensitivity to change. If an effect is observed in the outcomes measured, we will then be able to use the effect size to calculate an appropriate sample size for a future evaluation. In addition, we will test the feasibility of two different methods of collecting cost data.

Design

Using care home and NHS assessment unit settings available via co-applicants, we will examine the potential size of outcomes from and costs of using life story work, while exploring the feasibility of formal evaluation by piloting both a stepped wedge trial design and a pre-test post-test design, with controls.

None of our care home sites currently uses life story work, which allows us to test not just the feasibility of evaluation but also of rolling out the approach to new settings. A stepped wedge design, involves each setting receiving the intervention at some point during the period of the trial, and deals with likely pragmatic (delivering a complex intervention across a large number of settings at once is challenging) and ethical (all people with dementia should have the opportunity to benefit if our initial work suggests that this is likely) issues. Each setting provides both pre- and post-intervention data and acts as its own control whilst allowing secular trend data to be collected³⁷.

For practical reasons, the stepped wedge design can be applied only in the care home settings at this stage, because our NHS partner already implements life story work with all its assessment unit patients. However, we do have the opportunity, via the survey, to identify similar services that do not deliver life story work. A pre-test post-test design with a comparison group identified from the survey would thus offer the opportunity to address outcomes in and the feasibility of a non-randomised design.

In both designs, individual and system outcomes and costs will be examined, using quantitative and qualitative methods.

Methods

Settings

Setting 1: Six care homes not currently using life story work.

Setting 2: Three in-patient assessment units already using good practice life story work and three that do not.

Anchor will provide access to the care homes and facilitate introduction of life story work. Pennine NHS Trust will provide access to the assessment units currently using life story work (life story work is initiated when people enter the units and carries on when they return home or move into long-term care). The survey (see above) will allow us to identify and recruit comparable assessment units not currently using life story work.

This choice of settings, although pragmatic, does allow us to explore key factors that might influence outcomes: use of life story work at different points in the care pathway, in both health and long-term care settings, and in settings with established use of life story work and those introducing it for the first time.

Sample

Setting 1

Ten randomly selected residents with confirmed diagnosis of dementia (and their carer, if they have one) in each of six care homes in the Anchor group life story work will be introduced in one randomly selected home per month for a period of six months.

Setting 2

Ten people with confirmed diagnosis of dementia (and their carer) admitted sequentially to each of three in-patient assessment units that use life story work and three that do not.

Innovations in Dementia will facilitate informed consent processes for people with dementia. Usual consent processes will be used for carers.

Outcomes

We cannot describe outcomes, or the theorised causal links between them and life story work, until we have findings from Stage 1. However, literature and professional experience suggest that outcomes at the care setting level might include staff behaviour, stress levels and turnover, use of antipsychotic drugs, and adverse events; for the person with dementia, behaviour and stress levels, social interactions, and quality of life; and for carers perceptions of the impact of care giving, relationship with the person with dementia, and their own quality of life. Whatever outcomes are included in this stage, the European consensus document on outcome measures for psychosocial interventions in dementia³⁸ will influence the choice of appropriate instruments, for example, the use of DEMQOL if measuring quality of life. Professor Moniz-Cook, Chair of the INTERDEM group, will provide specialist advice in relation to choice of both outcome and baseline measures (see below).

Costs

To establish the costs of life story work relative to other approaches, relevant resource inputs will be identified, measured, and then valued using local or national unit costs, as appropriate.

Process

1) We will measure selected outcomes for all participants at baseline (for those in the life story work groups, before any life story work has commenced). Individual baseline measures for people with dementia and their carers will be included in care records and administered as part of routine admission assessment; if necessary, staff will be trained to use the measures. A project researcher will follow participants up at one-month, two months and six months after baseline, wherever they are then living. In this preliminary study we do not expect to be able to achieve blinding of outcome assessment and will take this into account in interpreting findings. We will also collect routine data on dementia diagnosis and severity at baseline and antipsychotic drug use and reported adverse events throughout. If stage 1 identifies outcomes for the care setting as a whole, including staff, we will also collect information about these for each setting at baseline and follow-up.

2) We will gather in-depth, qualitative information about their experiences of life story work and the processes involved in its evaluation from carers, staff and, if at all possible, people with dementia. The aims here are to develop qualitative understanding of causal links between life story work and outcomes in the quantitative element of the study, to explore the acceptability of the processes involved in evaluation of life story work and to understand any implementation issues, including barriers and facilitators to life story work and any unanticipated consequences (for example, disclosure of abuse) and how these can be managed. We will carry out face-to-face interviews with carers and, where possible, guided conversations with people with dementia, recruited to the outcome study, and focus groups with staff in the participating settings. Innovations in Dementia will advise on and, where feasible, facilitate conversations with people with dementia.

3) We will test the feasibility of two methods of collecting costs data: (a) routine records and (b) specially designed data collection forms for completion by staff. Identifying the main types of resources will be aided by discussions in the staff focus groups in Stage 1; they are likely to include: staff time for different types of staff, carers or volunteers; training for those who do the life story work; materials and private space for undertaking the life story work. Wider health and social care resource use will also be identified and measured, using an adapted version of the Client Socio-Demographic and Service Receipt Inventory³⁹. This will allow us to identify: general staff time not related to life story work; specific interventions (such as one-to-one care for challenging behaviour); treatments, including medication; referrals to professionals such as psychiatrists, psychologists, CPNs, social workers and GPs; referrals to other settings such as inpatient units; and lengths of stay or re-admissions to inpatient units or care homes. The involvement of family and other informal carers will also be measured.

Analysis

It is difficult to outline specific statistical tests before we know which outcome measures will be used. However, the overall approach for the assessment unit data will be multivariate analysis, controlling for any baseline differences, to measure differences between intervention and comparison groups at follow-up and change over time. For the care home data, the overall approach is likely to be a generalised linear mixed model approach, given the possibility of non-normal data and use of categorical variables⁴⁰.

Data on costs will be analysed to provide estimates of the costs of life story work, and the wider health and social care costs of study participants over the follow-up period. Although numbers in this initial feasibility study will be relatively small, the findings will give an indication of the size of the investment in life story work relative to potential savings from reductions in the use of other health and social care resources. Analysis will also indicate the main drivers of costs and the main differences in resource use in the two study groups

2.d Modelling costs and outcomes to inform a proposal for formal evaluation (objectives 3 and 4)

Using both qualitative and quantitative data from all elements of our study described above, we will create a narrative causal model that tries to explain if, how, and why life story work affects outcomes for people with dementia, carers and care staff/ settings. We will also have identified the likely cost parameters of implementing life story work in two different settings, current coverage of life story work at different points of the care pathway and have generated preliminary quantitative data on the efficacy of life story work. Using these preliminary data, we will then carry out quantitative modelling, following the process outlined by Eldridge et al⁴¹ to create a probability tree for effectiveness of life story work in relation to outcomes and then a Markov model of effectiveness and cost-effectiveness of life story work.

A probability tree estimates the effect of an intervention by 'all individuals start[ing] in the same state and the tree branches out in stages that represent states the individual can move onto. A probability is attached to the transition to each new state' (ibid, p.135). Before we collect information from all the prior stages of the project, and particularly before choice of outcomes for evaluation, it is impossible to determine the actual stages that will be included in our probability tree. However, to provide a speculative example, one might envisage the following:

Stage 1 How many people with dementia are in the care setting?

Stage 2 How many people with dementia in that care setting actually 'receive' full life story work?

Stage 3 How many people with dementia who have experienced full life story work in that care setting survive over 6 months?

Stage 4 How many people with dementia who have experienced full life story work experience a positive change in outcome at 6 months?

Effectiveness would then be estimated by multiplying the transition probabilities along each branch of the tree, showing the proportion of the original population that might be expected to experience a positive outcome from life story work at six months.

A Markov model will then be developed, using evidence from all the earlier stages of the project to construct transition paths (to better/stable or worse outcomes – Markov states), their transition probabilities (to construct a transition probabilities matrix), the utilities associated with the transitions and the costs of care. The 'treatment effect' will be modelled as a better/stable outcome, with any onward implications for the costs of care. The model will then be used to estimate the impact of life story work, over time, for a hypothetical cohort of 1000 people with dementia.

It is impossible to specify the pathways in the model, the outcomes that will be included, or the transition probabilities, utilities and costs associated with them before all the other stages of the work are carried out.

The results of this work will be used to judge the likely longer-term effectiveness and costs-effectiveness of life story work and, thereby, whether future formal evaluation of life story work would be viable or cost-effective. If such evaluation did seem to be viable and cost-effective, data from the feasibility study (2C above) would then be used to influence the design and methods, including sample size, of a future study proposal.

Contribution to collective research effort and utilisation

The project will have an impact plan that targets the main stakeholders of the research and brings main findings to the public and the NHS (**objective 5**). Specific high impact outputs for the project are:

A short film about the findings, designed and produced with the help of people with dementia and their carers, which will be available to the NHS and other dementia care providers and the public via SPRU and partner organisations' websites and shown at practice-oriented conferences.

A model of best practice for life story work that will be advertised and promoted to the NHS and other dementia care providers via our partner organisations.

Research Works summary disseminated to all health service providers and commissioners, other dementia care providers, and to relevant third sector organisations and members of the public.

Electronic presence of academic and practice findings on the SPRU website.

The main academic outputs from the study will be a theoretical model of life story work, who it works for and in what contexts, and an assessment of the feasibility of formal evaluation. The former will provide the basis for academic publication and the latter will (if evaluation proves feasible) inform development of a full proposal to NIHR.

Plan of investigation and timetable

- Months 1-8: initial ethics approvals; identify stage 1 samples; focus groups; carry out review; two advisory group meetings; one interim report.
- Months 10-12: Complete focus group data analysis; formulate theoretical model; identify outcomes, good practice and measures for stage 2; identify survey samples; design and pilot surveys; one advisory group meeting, one interim report.
- Months 13-22: full survey and analysis; design data collection processes for outcomes study; identify and consent samples for outcomes study; baseline data collection; one interim report; one advisory group meeting.
- Months 19-28: follow-up data collection; qualitative interviews for outcome study; analysis of both; any required refinement to life story work model; start work with film makers; one interim report.
- Months 29-30: model outcomes and costs to establish feasibility and design of formal evaluation; final advisory group meeting; final report.

Approval by ethics committee

Research with people with dementia raises complex issues of informed consent, but it is wrong to exclude them by assuming that none is able to give such consent. Innovations in Dementia practise a rights-based approach that supports people with dementia, including those with advanced dementia, to have their voices heard. People with dementia may need extra support to give informed consent and Innovations in Dementia uses various methods to help people understand and decide whether to participate in research. These methods may include: using visual props and cues; providing accessible written information to back up a consent discussion; routine reminders (verbal and/or written) that prompt people to reconsider and reflect on their involvement. Giving consent is an ongoing process. For people with dementia, visual cues such as body language may indicate that they want an interview to end. Researchers and Innovations in Dementia will work in partnership to ensure that best practice in gaining and maintain consent is achieved throughout the project.

Ethical issues arise in the remainder of the project largely through the need for sensitive interactions in individual interviews. We will deal with these issues first by our use of well-trained researchers, advised and supported throughout by our partner organisations. As is standard with research of this type, we will also produce information packs about the project, as well as packs to leave with participants after interviews, containing information about, and contact details of, sources of support. As part of our normal ethical practice, we would also explore with any participants who appeared distressed during interviews whether they would like us to put them into contact with further support. Issues of informed consent also apply to the professionals and care staff involved in the project, and information sheets and consent forms will be produced for them too.

All data obtained will be treated confidentially and according to SPRU's detailed data protection policies and procedures. No individuals will be identified directly by us in research outputs, and any specific details about people's circumstances that might make them recognisable to someone who knew them (for example, job title, unusual family circumstances) would be changed or omitted.

The project will require both research ethics committee and local research governance approvals, which we will obtain via the IRAS system. We will start the process of gaining approval for stage 1 before the project starts, to enable a rapid start to our work. Full approval for stage 2 cannot be granted until stage 1 has allowed us to choose which outcome measures will be used. We will make this clear when we apply for stage 1 approval. We are used to managing staged ethical

clearance processes, and to dealing with complex ethical issues with vulnerable groups.

Project management

Monthly meetings of the York-based research team will be the main day-to-day management tool for this project. Meetings will have agendas and minutes and will start in the first week of the project. We will use a Gantt chart to manage progress against objectives and timetable. The first and every fourth monthly meeting will be a project steering meeting when all co-applicants and our specialist advisor will attend, either in person or via telephone conferencing. Contact between all the applicants will be maintained between steering meetings via a secure, project specific, online networking site.

Kate Gridley will manage the project, taking day-to-day responsibility for overall progress and for the work with families and service providers; Professor Parker will mentor her throughout. Contributions of other applicants are outlined in the justification of support.

A project advisory group of relevant stakeholders, with an independent chair will meet on five occasions throughout the project. Members include Martin Orrell, Professor of Ageing and Mental Health, University College London and representatives of a range of third sector organisations. Two advisory groups of people with dementia and of carers will advise and inform the project throughout (see below).

Public involvement

SPRU has a long-standing commitment to involving service user and carers in its research. Participatory consultation groups meet regularly with us to share their ideas for future research, and advise on proposed work, design of research instruments and processes, implications of results and effective ways of disseminating findings. We have consulted the group about this proposal and received their support for the topic and the approach.

It is our standard practice to include service users or carers in advisory groups for individual projects. For this project, Innovations in Dementia will recruit and facilitate a virtual advisory group of people with dementia whom they will consult in person. Similarly, Uniting Carers will recruit, facilitate and consult a virtual advisory group of carers. These groups will provide advice throughout the project. Representatives of

both organisations (other than the co-applicants) will attend project advisory group meetings (see above) to feed in the views of both virtual advisory groups.

The strongest evidence of public involvement in this project is the range of co-applicants involved and the virtual advisory groups. However, SPRU has strong links with other third sector representative organisations, some of whom will be represented in our project advisory group. We will also disseminate widely to user organisations and representatives and work with them to relay research messages in appropriate formats.

Expertise

This is a joint project between organisations of and for people with dementia and their carers, NHS and third sector service providers, clinicians, and experienced health and social care researchers at the University of York. The project is based at York, and steered by co-applicants.

Applicants

Ms Kate Gridley (SPRU): Research Fellow, undertaking core research and project management activities throughout the project and supervising the part-time researcher. Expertise is in health and social care research, including systematic reviews, with a professional background in health service commissioning and service improvement. Current and recent work includes evaluation of care closer to home for children and young people who are ill, evaluation of the National Service Framework for Long-Term Neurological Conditions and a study of innovations and practice supporting people with complex and severe needs, including dementia.

Professor Gillian Parker (SPRU): Director of SPRU, acting as a systematic reviewer, managing the analysis of quantitative data, mentoring Ms Gridley, and taking final responsibility for ensuring that project milestones and budget are met. Expertise is in applied social research in health and social care; methods expertise includes secondary data analysis, qualitative and quantitative approaches to service evaluation, and systematic reviews of complex interventions. Current and recent research includes outcomes in integrated care for long-term neurological conditions and evaluation of care closer to home for children and young people who are ill.

Dr Kate Baxter (SPRU): Research Fellow, providing advice on economic data collection and modelling. Expertise is in the design and implementation of economic evaluations of health and social care interventions, and design of collection and analysis of data for the calculation of the unit costs of care processes.

Dr Victoria Allgar (Hull York Medical School): Senior Lecturer and lead of the HYMS Statistical Consultancy service, providing statistical advice and designs, statistical analysis plans, high quality analyses, and associated statistical programming for checking, manipulating and summarising data.

Dr Yvonne Birks (Health Sciences, University of York): Senior Research Fellow and member of York Trials Unit, providing research methods advice, particularly in relation to feasibility and design of formal evaluation. Has a nursing and psychology background, working in research for 10 years. Expertise is in multi-centre trials and measurement issues in elderly populations.

Jean Tottie: Chair of Uniting Carers at Dementia UK and a director of the Life Story Network. Occupational therapist with a track record in service improvement in health and local authority settings. Led on implementation of the NSF for Older People for NHS Northern & Yorkshire and helped to set up the first Dementia Services Collaborative. Was carer representative for the External Reference Group of the National Dementia Strategy and is now a member of the Implementation Reference Group. Steering group member for Kirklees Admiral Nursing Service and the Royal College of Psychiatrists' Memory Services Accreditation Programme.

Joy Watkins: Co-ordinates Dementia UK's national network of family carers, *Uniting Carers*, developing opportunities to enable carers to make a difference to the quality of services provided for people living with dementia and for carers. Believes that family carers have a vital role to play in increasing awareness and understanding of dementia and its impact on those that care for them. Has worked in the voluntary sector for many years, most recently in HIV& AIDS and Crossroads Caring for Carers. She has experience in training and skills development, with particular interest in carer, service user and volunteer involvement.

Polly Kaiser: Clinical lead for psychological therapies for older people at Pennine Care NHS Foundation Trust. Teaches on doctoral training programmes for clinical psychologists and sits on the national faculty of old age psychology (PSIGE). She has worked with people with dementia for 27 years, first as a researcher and then as a clinical psychologist. Was national lead for mental health in later life for the Mental Health Equalities Programme (DH National Mental Health Development Unit). She is a member of the nationally recognised Oldham Life Story Group, and was a member of the national life story steering group.

Victoria Metcalfe: Dementia Care Consultant at Anchor, 30 days. Has worked with, and for, people with dementia for nearly 25 years. Her commitment to improving

people's experiences in this area developed through her time working at Newcastle Social Services Department, when she undertook training with Tom Kitwood. Worked for 10 years with the Alzheimer's Society before her current post in which she leads on dementia service development across Anchor's 100 care homes and provides expert advice on dementia care matters.

Nada Savitch: Innovations in Dementia, Director. Innovations in Dementia tests opportunities to enable people with dementia to live life to the fullest, promoting a more positive view of dementia and believing that with the right support and opportunities, people with dementia can communicate, engage, participate and continue to be part of relationships and communities, no matter how advanced their dementia. Much of her work supports people with dementia to have a voice in the design of products and services developed for them. Ten years' experience in working collaboratively with people with dementia and producing accessible information.

Specialist advisor

Professor Esme Moniz-Cook: Consultant Clinical Psychologist, Humber NHS Foundation Trust/University of Hull, providing specialist advice on the intervention outcome measures in dementia care. Specialist experience is in psychosocial intervention across the dementia trajectory. She is founder member and coordinating Chair of INTERDEM, a pan-European interdisciplinary network of dementia care research-practitioners.

Other support

Grade 6 researcher, (to be appointed) collecting quantitative data in stage 2.

Project administrator, to provide all aspects of administrative support to the project, including project diary management, arranging travel and accommodation, arranging and taking minutes for project and advisory group meetings, production of paper and electronic research materials, and final production of interim and final reports.

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