Health risks and benefits of extended working life (the HEAF Study): Project protocol

Summary

The need to keep Britain's ageing population economically active has prompted government policies aimed at extending working lives. However, working beyond the traditional retirement age may not be feasible for those with major health problems of ageing, and depending on occupational and personal circumstances (e.g. savings, retirement intentions, domestic responsibilities, whether work is arduous, rewarding), might be either good or bad for health.

We will recruit 6,000 50-64 year-olds from approximately 18 practices contributing to the Clinical Practice Research Datalink (CPRD, formerly GPRD). Participants will complete questionnaires about their work and home circumstances, initially over a 3-year follow-up, and with their permission, we will access their health data via the CPRD. The inter-relation of changes in employment (with reasons) and changes in health (e.g. major new illnesses, new treatments, mortality) will be examined.

CPRD linkage offers major advantages, notably cost-effective capture of frequent, detailed, objective health data. We will be able to examine the impact of health on work at older ages (e.g. how often arthritis suffers have to quit work) and of work on health (e.g. whether mental health is helped or worsened by deferring retirement, and in what circumstances). Findings should inform government policy and improve the design of work for older people.

UPDATE 16/12/2015: As the HEAF study has been progressing so well with an engaged group of participants (over 80% response rate on the first full follow-up and a similar response on the second follow-up - currently underway), we propose to continue the study for a further three years to add further value to the research.
As we initially obtained consent for ongoing access to anonymised NHS health records and consent to send participants three follow-up questionnaires, we propose to send a further consent form with the third follow-up questionnaire asking for consent to be sent follow-up questionnaires for the next three years. There are no changes to any other ethical aspects of the study (e.g. information given to participants, method of recruitment, confidentiality, security of data etc), only renewed consent.

UPDATE 10/04/2014: The recruitment number has been modified to approximately 8,000 patients. This arises by chance rather than design. Response rates were initially lower than hoped for. It was therefore necessary to increase the size of the mailout. However the response rate subsequently proved higher than budgeted so we have actually secured more responses than originally planned for at baseline. We feel it would be unethical now to discard the additional responses. Indeed, they will increase the power of the study (ie its ability to analyses associations of interest robustly), making the effort of participants even more likely to count. There are no changes to any of the ethical aspects of the study (e.g. information given to participants, method of recruitment, consent, confidentiality, security of data etc), only a higher number recruited.

The protocol below is unchanged, therefore, apart from an update on numbers which are highlighted in bold.

Background

During recent decades, the proportion of the British population aged 50 years or older has steadily grown. There is therefore an economic imperative to keep people productively in work to older ages, and various government policies have been developed to boost labour force participation among older people (e.g. raising the state pension age, abolition of the default retirement age, and prohibition of unjustified age- and disability-discrimination in the workplace). At the same time, increasing numbers are intent on working longer, to build savings for retirement in the face of personal indebtedness, higher costs and taxes, and diminishing returns on savings and pensions.

Work at older ages may carry physical benefits to the individual, such as maintained muscle strength and mobility; and psychological benefits, such as sustained motivation and sense of purpose, social engagement and mental activity.[1] Additionally, work may provide the wherewithal to support self and dependants and improve social cohesion in communities. Set against this, older workers may struggle with the physical and psychological demands of work,[1] while their greater prevalence of illness and greater use of medication could impose added risks of injury and mishap in the workplace.[2] Moreover,

planned normal retirement may carry tangible health benefits of its own[3-6] and foregoing it may be bad for psychological health. There is thus uncertainty about the overall health implications of policies to extend working life and maximise employment at older ages. Quite possibly, outcomes will vary with circumstances – e.g. the nature of an individual's work (e.g. physically or mentally demanding vs. less so, rewarding vs. disliked), their retirement expectations, personal savings, and social circumstances (e.g. carer responsibilities, social networks); and a few studies suggest effect modification of this kind. Knowing the factors that predict a better or worse outcome will become increasingly important in designing suitable work and social support for older workers.

A second major area of uncertainty concerns the extent to which common health problems limit work participation at older ages. For example, among the diseases of ageing, those affecting the musculoskeletal system, such as osteoarthritis, soft tissue rheumatism, and disorders of the back, neck, upper limbs and knee cartilage – may limit late-career capacity for work (although the evidence base on this is presently small[7]). Again, the context is likely to be important, some work circumstances being more forgiving of health limitations than others.

A third uncertainty, given the rising prevalence of age-related disorders and their treatments in modern workforces, is the associated risk to physical safety and the jobs that older workers can and cannot safely perform. A systematic review of health and risk of occupational injury[8] has highlighted the paucity of data and the difficulty managers will have in setting evidence-based employment policies.

Effective planning to maximise work opportunities at older ages also requires information on the descriptive epidemiology of ageing and adverse employment outcomes. Thus, it would be helpful to know: how often middle-aged adults quit a job for medical reasons, and which disorders are most often responsible; the levels of sickness absence in older workers from the general population and its leading causes; how well medical factors and indices of mental and physical health predict sickness absence and job loss; the likelihood that an older adult who quits a job for medical reasons will find re-employment, and how this varies by reason for job loss; how patterns of job loss vary by type of work and how much they are modified by workplace psychosocial and physical conditions and access to rehabilitation services. Only limited data on these questions are available at present, but all are important and pressing, given the changing demographics of the workforce.

Against this background we have been funded to assemble a new cohort of older people, nested within Clinical Practice Research Datalink (CPRD) (formerly the GPRD), which is owned by the Medicines and Healthcare Products Regulatory Agency, an executive agency of the Department of Health. Since 1987 the CPRD/GPRD has provided a log of all consultations associated with significant events, illnesses, or medical activity (diagnosis, referral, prescription, etc) among patients in participating general practices. Data are uploaded regularly by the CPRD and screened for completeness (>97%) and validity (high in external audits).[9-11] Events are linked at the individual level via unique identifying code numbers. Although health data are well captured, occupational data are not, and need to be ascertained by other means. We propose a new prospective cohort, nested within the dynamic patient population registered with the CPRD. CPRD-linkage offers major scientific and logistic advantages in relation to our study questions, notably cost-effective capture of frequent, detailed, objective health data.

Objectives

1. To assess the health benefits and risks of remaining in work at older ages and their predictors (health as an outcome), and thereby the health impact of policies to extend working life and maximise employment in later working life; to identify occupational, social and personal co-factors which modify this relationship.
2. To assess the impact of health on employment outcome and lost work time (health as an exposure) - e.g. the impact of musculoskeletal illness at older ages on work capability, employment status, and job retention.

The study will also lend itself to:

3. Assessing the effect of common health problems of ageing on risk of workplace injuries (health as an exposure with injury as an outcome).
4. Mapping the descriptive epidemiology of ageing and employment transitions.

Study design: Observational prospective cohort study.

Plan of investigation:

Study population – We will recruit approximately 8,000 patients aged 50-64 years registered with general practices currently participating in CPRD data collection. Some 24 practices will be needed, assuming list sizes corresponding to the national average and the response rate set out in the power calculations below (numbers above changed after initial piloting in two of the centres). The location of these practices will depend on the willingness of GPs to support the study. Ideally, however, there will be purposive quota sampling aimed at ensuring a reasonable geographical spread e.g. at least 25% of total list size from each of the South, Midlands and North. We consider this sensible as unemployment rates and patterns of illness behaviour and consulting will vary geographically. However, there is no requirement that the distribution of respondents' occupations should be nationally representative.
Subjects will receive a questionnaire at baseline and a briefer questionnaire at follow-up (annually for 3 years initially). The age limits have been chosen on the expectation that some subjects will already be retired at baseline, some will retire at follow-up with others deferring retirement, and many will develop retirement plans. No other inclusion or exclusion criteria are envisaged - all patients in the relevant age band from each participating practice will be invited to participate for the duration of follow-up.

The questionnaire at baseline will ask about: 1) current work status; 2) among those in paid work – main occupation, length of service, pattern of work (e.g. salaried vs. piece work, permanent vs. temporary), employer's size, physical and psychosocial working conditions (e.g. kneeling, climbing, digging, heavy lifting, standing, shift and night work, work demands and support), job satisfaction, conflicts at work, job security, income protection in illness; self-reported ability to cope with work demands); 3) financial status (e.g. contribution to total household income, housing tenure, affordability of consumer durables, pension provision; 4) attitudes to work and retirement – how long the person would like to work, how long they need to work, their intended retirement age; 5) demographic, social and anthropometric data – education and qualifications, marital status, dependants and caring commitments, household composition, height and weight; 6) leisure and social activities; 7) smoking and alcohol history; 8) selected health items: sickness absence in past 12 months; regional pains in past 12 months; Self-Rated Health (SRH); abridged Sleep Problems Scale; Brief Symptom Inventory (BSI) somatising scale; Center for Epidemiologic Studies Depression Scale (CES-D);and the Warwick-Edinburgh Mental Well-being Scale (MWBS); brief items on items on frailty (Fried frailty index) and cognition.

The follow-up questionnaire will assess changes from baseline in: 1) job circumstances, with reasons (job loss, new job, job modification, for health-related or other reasons); 2) health (e.g. hospital referrals, new diagnoses, new treatments, new workplace injuries, changes in SRH, BSI, CES-D, MWBS, frailty, cognition); and 3) attitudes towards retirement (including those modified by spouse's health and employment).

The CPRD will provide the main source of information on health at baseline and over follow-up. Taking musculoskeletal and metal health problems as examples: consultation episodes are classified by the hierarchical Read diagnostic coding system, enabling diagnoses to be defined broadly (e.g. Read code N: Musculoskeletal and connective tissue diseases; E: Mental disorders), in fine divisions of detail (e.g. N211: rotator cuff syndrome; N143: sciatica; N2165: prepatellar bursitis; E112: major depressive episode), and where relevant in functional or symptomatic terms (e.g. N3371 complex regional pain syndrome; N131: chronic/recurrent neck pain). Similarly, GPs' prescriptions are logged using British National Formulary codes, from broad categories (e.g. 10.3: Drugs for the relief of soft-tissue inflammation) down to specific formulations, doses, and durations of treatment. In a separate scoping exercise, we have determined a suitable coding framework for consultations linked with occupational injury.

We will focus on the following items from the CPRD record:

- All hospital admissions, including all discharge diagnoses and procedures
- All GP consultations for musculoskeletal disorders
- All GP consultations for mental health problems
- All GP consultations for asthma or COPD
- All GP consultations for cardiovascular problems
- All GP consultations for diabetes and epilepsy
- All prescriptions related to these health problems (e.g. anxiolytics, hypnotics, sedatives, antidepressants, antipsychotics, narcotics, circulatory drugs, insulin, oral hypoglycaemics, antiepileptic medicines)
- All injuries specified as occupational (as defined above)
- Frequency of GP consultations from all reasons combined

- Any records of height, weight, BMI, smoking habits, alcohol consumption.

Validity of measuring instruments: Several of the chosen measuring instruments are widely used standards and/or have established acceptable psychometric properties. For example, the SRH is a predictor of mortality and morbidity;12 the CES-D has high internal consistency, and adequate test-retest repeatability and concurrent and discriminant validity;13 the somatic subscale of the BSI14 predicts incident and persistent regional pain;15 the Warwick-Edinburgh Mental Well-being Scale has been evaluated for internal consistency, test-retest repeatability, and content and construct validity,16 and questions on work coping and sickness absence derive from the well-respected Work Ability Index. Chosen questions on frailty and memory have been predictive of poorer physical health (falls, reduced mobility, hospital admissions) and of cognitive decline respectively.

Analysis: Analysis will look at health conditions (e.g. MSDs) as predictors of work outcome, i.e. the effect of MSDs on work capacity, employment status and job retention). Also, however, as the timing of events within the CPRD database is recorded for ill-health classified across a panoply of diagnoses, more complex causal chains can be examined, such as the impact that MSD-related job loss might have on subsequent short-term mental health, or the impact of job loss or retention at older ages on mental health. Thus, with health and employment, assessed at various time points (T1, T2,... Tx), and denoted at each time point by H1, H2..Hx and E1, E2,...Ex respectively, or by changes in these measures (ΔE1-2, ΔH1-2, etc):
a) We will assess cross-sectional associations between (i) health and employment status (H1 vs.E1), (ii) change in health and later employment status or employment transition (ΔH1-2 vs. E2, ΔH1-2 vs. ΔE1-2), and (iii) employment transition and later health or change in health (ΔE1-2 vs. H2, ΔE1-2 vs. ΔH1-2).
b) Also, we will assess the longitudinal relationship between (i) health (or health change) and employment transition (H1 vs. ΔE1-2, ΔH1-2 vs. ΔE2-3 etc), and between (ii) employment transition and changed health (e.g. ΔE1-2 vs. ΔH2-3). In longitudinal analysis, multi-level modelling will be used to estimate such effects with allowance for other personal and social factors acting as confounders or effect modifiers. Table 1 summarises certain health circumstances and our intended treatment of them. Analysis will also explore health and medication as predictors of occupational injury.

Table 1: Some independent and dependent variables likely to feature in analysis (taking MSDs as a focus)

a) Effect of health on work:

Predictor variables

Health or change in health

1) CPRD record: diagnosis (or treatment/worsening) of arthritis, soft tissue rheumatism, or other MSDs; or in those with MSDs, of concurrent... anxiety, depression, neurotic illness, insomnia, cardiovascular disease, new hospital treated illnesses etc.
2) Questionnaire: in those with MSDs: change in pain symptoms, SRH, SF-36, CES-D, BSI, MWBS, sleep problems

Outcome variables

Employment status: unemployed, retired, ill-health retired, temporarily off sick, employed, other role (e.g. carer)
Employment change: (new) involuntary job loss; planned normal retirement; early planned retirement; early ill-health retirement; re-employment

b) Effect of work on health:

Predictor variables

Employment status: unemployed, retired, ill-health retired, temporarily off sick, employed, other role (e.g. carer)
Employment change: (new) involuntary job loss; planned normal retirement; early planned retirement; early ill-health retirement; re-employment

Outcome variables

Change in health

1) CPRD record: new diagnosis of, or treatment for, worsening/recovery from … anxiety, depression, neurotic illness, insomnia, cardiovascular disease, hypertension; new hospital treated illnesses; altered frequency of GP visits

Sample size/study power: The retirement rate among 55-64 year olds in the 2001-2 wave of the nationally representative British Household Panel Survey was 8.28% and the unemployment rate was 1.73%.[17] Taking the annual incidence of first consultations for osteoarthritis for 45-64 yr-olds published in the 4th Morbidity Survey in General Practice[18] as a guide to the rate at 55-64 years, then a RR of 1.53 for retirement or unemployment within a given year would be detectable with an alpha of 0.05, a power of 80%, a sample size of 6,000 and the events in one year of observation. In practice, aggregated observations over 3-5 years will offer much greater study power, even after allowing for correlated observations within individuals, sufficient to consider less common incident consultations. To recruit 6,000 adults aged 50-64 years (assuming conservatively a 30% response rate) we will approach 20,000 adults. An average practice in England has a list size of 6,250,[19] while 50-64 year-olds comprise ~17.8% of the list or 1113 of those in a typically-sized practice; thus, we will enlist some 18 practices to mail to 20,000 people and to engage 6,000 in follow-up. (If take up rates fall short of expectations, we will approach other practices and patients to meet the target.)

Logistics; potential limitations in design
This study involves a novel use of the CPRD database: prior studies have employed registry-based surveillance, nested case-control analyses, and a randomised trial; but not thus far observational follow-up of a cohort. However, there are grounds for expecting the approach to succeed:

1. The success of recruitment at baseline is not contingent on a high response rate, either among practices or individuals. (This is because we plan to recruit only 6,000 subjects from an estimated 278,250 patients aged 50-64 years enrolled with the 250 practices in England participating in the CPRD; where practices or individuals decline to be involved we will approach other practices and individuals until the baseline target is met).
2. The important response rate for judging internal validity is not that at baseline but that at follow-up, as explained in standard texts (e.g. Hennekens & Buring. *Epidemiology in Medicine*, 5th edn 1987, p37 & p171) and increasingly recognised by those critiquing major community surveys such as the Biobank Study. Losses to follow-up are a primary concern, and in this respect we have achieved high response rates in previous prospective cohort studies run from the MRC LEU.
3. We have experience of managing and processing large scale postal surveys, such as that proposed at baseline (20,000+ subjects).
4. The MRC LEU has expertise in successfully managing large scale complex follow-up studies (such as the Southampton Women's Study and the Hertfordshire Cohort Study) and was highly rated in all of its programme activities at its last quinquennial external review.
5. The MRC LEU, in partnership with the University of Southampton South Central Research Design Service (RDS), has established an infrastructure specifically to manipulate the large datasets that arise from GPRD collaborations. This infrastructure and our partnership with Prof Tjeerd van Staa (Director of Research at CPRD, a visiting Honorary Senior Clinical Research Fellow with the MRC in Southampton, and a co-grant holder) have proved fruitful in investigations of fracture risk and resulted in several high profile publications, demonstrating our capacity to exploit the GPRD database. The RDS will provide training and support to MRC data management and statistician appointees, to ensure cost-effective processing of a very large data set.
6. We will *pilot* data collection in two of the participating practices before recruiting more widely, but we consider the execution risk acceptably low with careful preparation.

We discuss the issue of selection bias, arising from incomplete recruitment and follow-up, above (1 and 2). Recall bias is unlikely to pose a problem as all subjective inquiries will be made prospectively, ahead of study outcomes, while some data by their nature (e.g. employment status) are likely to be reported reliably, and most health data will be assembled from the independent medical record. Measurement error will also be reduced to the extent that some items are easy to self-report, several measuring instruments are validated (see above[12-16]) and many measures come from the CPRD record, which has been shown previously to be well completed with high validity in external audits.[9-11] (Measurement errors may more plausibly arise in relation to subjective items in the questionnaire (e.g. self-reported satisfaction with work), but typically these items will be used prospectively as predictors, suggesting that the bias, if any, will be to the null.) Confounding will be addressed to the extent that data on a wide range of other predictors of outcome (whether job status or health outcome) will be collected through questionnaires and CPRD records and will be adjusted for in multivariate analysis.

Ethical approvals and permissions

An application is being made via IRAS for a national ethics approval covering participating practices in England, as the study will necessarily involve patient contact. (We have secured CSP portfolio registration and the Hampshire & Isle of Wight CLRN has offered to facilitate NHS R & D approval when the participating practices are identified.) Permission to access the CPRD has required separate application to the CPRD's Independent Scientific Advisory Committee (ISAC).

Lay involvement
The grant funder, *Arthritis Research UK*, includes a lay assessment component/peer review in relation to all of its grant applications. Lay feedback through this route contributed to a revised application protocol. Similarly, we have responded to lay comments conveyed via the CPRD's ISAC. A number of the measuring instruments have already been used successfully in general population surveys.

Peer review
The study protocol has been peer reviewed previously both by *Arthritis Research UK* ahead of its grant award (2011) and by a visiting scientific panel plus external referees appointed by the MRC to assess the Unit's programmatic funding on Work and Health (2010 quinquennial review). This proposal was supported and commended.

Dissemination and communication of results
Through peer reviewed scientific publications, presentations at scientific meetings, and the Arthritis Research UK's publicity network. The results will be made available to the MRC to inform the part of its Lifelong Well-being Programme, now focussed on extended working life; and we have established contact with the division in DWP responsible for this area of government policy.

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