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Randomised controlled trial, economic and qualitative process evaluation of domiciliary welfare rights advice for socio-economically disadvantaged older people recruited via primary health care (The Do-Well Study)

Chief investigator	Professor Martin White
Sponsor	NHS North of Tyne
Funder	PHR Programme
NIHR Portfolio number	
ISRCTN registration (if applicable)	To be confirmed

Randomised controlled trial, economic and qualitative process evaluation of domiciliary welfare rights advice for socio-economically disadvantaged older people recruited via primary health care

The Do-Well Study

ISRCTN Number: to be confirmed

REC Reference: 11/SW/0260

Protocol Version 1.0

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Sponsored by NHS North of Tyne

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Study website:

http://www.fuse.ac.uk/group.php?gid=157&pid=2532
http://www.ncl.ac.uk/ihs/

2. Protocol Signature Page

2.1 Protocol authorisation signatories

Signature …… Date ……

Professor Martin White, Chief Investigator

Signature …… Date ……

Ms Denise Howel, Statistician

Signature …… Date ……

Dr Katie Lock, Project Manager

2.2 Chief Investigator signature

I confirm that I have read and understood protocol version 1.0 dated 24th August 2011. I agree to comply with the study protocol, the principles of GCP, research governance, clinical trial regulations and appropriate reporting requirements.

Signature …… Date ……

Professor Martin White, Chief Investigator

3. Contents Page

4. Glossary of Abbreviations

Abbreviation	Definition
CASP 19	The acronym stands for the four domains of control, autonomy, self-realization and pleasure
ELSA	English Longitudinal Study of Ageing
GCP	Good Clinical Practice
GP	General practitioner
HAZ	Health Action Zone
MIHL	Minimum income for healthy living
NIHR	National Institute of Health Research
PCRN-NY	Primary Care Research Network – Northern and Yorkshire
RCT	Randomised controlled trial
SF-36	Short Form - 36
WRA	Welfare rights advisor

5. Responsibilities

Sponsor: NHS North of Tyne will act as the sponsor for this study.

Funder: The NIHR Public Health Research programme is funding this study.

Study Management: A Study Management Group (SMG) will be appointed and will be responsible for overseeing the progress of the study. The day-to-day management of the study will be co-ordinated by Dr Katie Lock.

Chief Investigator: This is a single-centre study and the Chief Investigator will have overall responsibility for the conduct of the study at this site.

Study Management:

The following functions falling under the responsibility of the sponsor will be delegated to Professor Martin White as the Chief Investigator:

- Ethics Committee Opinion (including application for research ethics committee favourable opinion, notification of protocol amendments and end of trial, site specific assessment & local approval)
- R&D Approval (including application for global checks, via NIHR CSP)
- Good Clinical Practice and Trial Conduct (including GCP arrangements, arrangements for trial oversight, data monitoring)
- Administration of funding for the study

Trial Conduct:

Investigator responsibilities:

- Study conduct and the welfare of study participants
- Familiarity with the study intervention(s).
- Compliance with the protocol, documentation of any protocol deviations and reporting of all serious adverse events
- Screening and recruitment of participants
- Obtaining local approval and abiding by the policies of Research Governance
    - Assistance will be provided by Primary Care Research Network, Northern & Yorkshire
- Compliance with the Principles of GCP, the Research Governance Framework for Health and Social Care, the Data Protection Act and any other relevant legislation and regulatory guidance.
- Ensuring that no participant is recruited into the study until all relevant regulatory permissions and approvals have been obtained.
- Obtaining written informed consent from participants prior to any study specific procedures.
- Availability for Investigator meetings, monitoring visits and in the case of an audit.
- Maintaining study documentation and compliance with reporting requests
- Maintaining a site file, including copies of study approval, list of participants and their signed informed consent forms
- Documenting appropriate delegation of tasks to other study personnel (e.g. Research Nurse, Co-Investigator(s), Trial Coordinators, Data Managers)
- Ensuring data collected is accurate, timely & complete
- Providing updates on the progress of the trial
- Ensuring participant confidentiality is maintained during the project and archival period
- Ensuring archival of study documentation for a minimum of 15 years following the end of the study, unless local arrangements require a longer period

6. Protocol Summary

Short title:	The Do-Well Study
Protocol version:	1.0
Protocol date:	24th August 2011
Chief Investigator:	Professor Martin White
Sponsor:	NHS North of Tyne
Funder:	NIHR Public Health Research
Study design:	Individual randomised, single blinded, wait-list controlled trial, with economic and qualitative process evaluations
Study Intervention:	Welfare rights advice consultations and active assistance with benefit claims offered and delivered in participants' own homes, tailored to individual needs, by a trained welfare rights advisor employed by adult social services departments in North East England
Primary research question:	What are the effects on health-related quality of life of a domiciliary welfare rights advice service targeting independent living, socio-economically disadvantaged older people (aged ≥60 yrs)?
Secondary research question:	• What are the cost consequences and what is the cost effectiveness of a domiciliary welfare rights advice service targeting independent living older people? • What is the acceptability to trial participants and relevant professionals of a domiciliary welfare rights advice service targeting independent living older people? • What are the unanticipated consequences (positive and negative) of a domiciliary welfare rights advice service targeting independent living older people?
Primary outcome:	Quality of life, measured using the CASP 19 questionnaire
Number of study sites:	1
Study population/size:	Volunteer men and women 60 years and over (1/household) identified from GP patient registers. Patients in nursing homes or hospitals will be excluded. GP populations in disadvantaged areas of North East England, including urban, rural and semi-rural areas, with no previous access to targeted welfare rights advice services delivered to primary care patients. A minimum of 750 participants will be randomised to intervention and control arms
Study duration:	42 months

7. Background

7.1 Existing research

Socio-economic inequalities in health, income and older people

Health inequality is one of the most enduring problems of our time.[1 2 3] Socio-economic differences in health persist into old age and social inequalities in self-reported physical and mental health widen in early old age.[4] The poorest older people have inadequate access to services essential to health and well-being.[5] Those in poorer socio-economic circumstances are more likely to retire early as a result of ill-health,[6] resulting in fewer resources available for retirement. Income inequalities among older people are also widening.[7] It is predicted that the proportion of over 65s living in poverty in the UK will remain at around 20% between 2007-08 and 2017-18.[8] A 'minimum income for healthy living' (MIHL) in older age has been proposed, derived from evidence on diet and nutrition, physical activity, housing, medical care entailing out-of-pocket costs, psychosocial relations and social inclusion. The estimated MIHL is 50% higher than the current state pension and appreciably higher than the official minimum income safety net.[9] A considerable body of research, including that undertaken by the applicants, demonstrates that older people, especially those in poor health, are more likely to require additional income and support, including payments for care, domestic help and aids and adaptations to the home.[10-12]

Resource-based interventions to promote health

The vast body of evidence on socio-economic inequalities in health suggests a close relationship between access to resources and health status. Increasing an individual's or group's access to material, social or financial resources should result in improved health,[13 14] yet little research has directly evaluated the impact of increasing resources on health.[15] Reviews of interventions aimed at reducing inequalities in health[16-19] have found few successful approaches, mostly limited to increasing uptake of preventive services or increased knowledge of healthy behaviours. Gunning-Schepers concluded that *"... many of the more structural interventions are likely to be considered and implemented outside the health sector".*[19] A systematic review of ten North American randomised controlled trials of income supplementation experiments targeting a range of age groups, carried out in the late 1960s and 1970s, showed that none had reliably assessed the effects of increased income on health.[15] The authors pointed out that, although such experiments are unlikely to be repeated, one way of assessing the health impact of increasing financial resources on health lies with assisting claimants to obtain full welfare benefit entitlements.[15]

Tackling health inequalities has become a major policy priority for government, highlighted, for example, in the white papers on tobacco control (Smoking Kills)[20] and on public health (Saving Lives: Our Healthier Nation).[21] In 1999, the Department of Health published Reducing Health Inequalities: an Action Report, which outlined policies and interventions to address the issue. Current government policy on tackling inequalities in health is awaited, following the publication of the Marmot report in April 2010 and the election of a new government in May 2010.

Social welfare for older people and under claiming of entitlement

In the UK, large amounts of social welfare benefits go unclaimed,[22 23] and a disproportionate amount of these are the health-related benefit entitlements of vulnerable groups, such as older people.[24 25] Failure to claim entitlements is linked to a number of factors including the complexity of the benefits system,[26] lack of knowledge about entitlements and difficulty in making claims.[12 27-29] In addition to the state pension, there are a number of means tested and non-means tested benefits that can be awarded if entitlement conditions are fulfilled. The level of under claiming varies depending on the benefit concerned. It is estimated that one third of entitled pensioners fail to claim Pension Credit, a means tested benefit introduced in 2003 to provide a minimum income level for pensioners. Moreover, the number of non claimants has risen over the last decade from 25 per cent to 35 per cent.[30] There are a number of benefits that are intended to compensate for care needs resulting from illness or disability, and these are also persistently under claimed. Berthoud et al have estimated that at least 30 per cent of people aged over 65 who are entitled to receive Attendance Allowance do not.[31] Entitlement to one benefit can often act as a 'passport' to other benefits, since many of the benefits aimed at people over state retirement are linked together in a complex network of entitlements that are often difficult for people to access without expert assistance. In our pilot RCT, we found that facilitating access to a domiciliary welfare rights service, delivered to older people (aged ≥60 years) recruited from primary care, increased uptake of financial (e.g. Attendance Allowance or Pension Credit)(median gain £55/week) and non-financial benefits (e.g. aids and adaptations to the home) in 58% of participants.[11]

Welfare rights advice services and their evaluation

Welfare rights advice provided by social services and Citizen's Advice Bureaux, and some other charities and voluntary organisations, is known to increase uptake of benefits, particularly where this involves 'active assistance' with benefit claims.[28 32] Studies have also shown that receipt of benefit entitlements can be increased by providing information and advice in general practice, particularly in relation to those benefits that are health-related.[33-37] Of the two studies that have investigated the health impact of welfare rights advice,[38-40] one found an improvement in health-related quality of life measured by the SF36.[38 39] However, both studies demonstrate the difficulties of identifying and measuring appropriate health outcome measures in studies assessing the health effects of welfare rights advice in primary care.[38-40] Neither study used a randomised controlled design and both suffered from significant methodological weaknesses that render them inconclusive. In qualitative studies, exploring the impact of welfare rights advice on clients in primary care, we identified that a range of health-related outcomes can potentially result from receipt of welfare rights advice, including changes in physical, behavioural and, in particular, psycho-social domains of health.[12 27-29]

Following publication of the Acheson Report[2] and the advent of Health Action Zones (HAZs),[41] there was an increase in welfare rights advice projects linked to primary care. The National Association of Citizen's Advice Bureaux estimated in 2000 that there were 132 welfare rights advice services targeted to primary care patients in England.[42] More recently, in 'Reducing Health Inequalities: an Action Report',[43] welfare rights advice was highlighted as a potentially effective intervention to reduce health inequalities. This was subsequently endorsed in the Marmot Review.[3]

We conducted a pilot RCT to prepare for the definitive RCT proposed here, evaluating the impact of a domiciliary welfare rights advice service offered to people aged over 60, identified via primary care in disadvantaged areas.[11 12 44] This pilot confirmed the feasibility and success of the intervention, from the point of view of accessing unclaimed benefits, and provided useful information on the feasibility of such a trial, which has helped in the planning of the current definitive RCT. Below, we discuss some of the methodological issues raised by the pilot and explain how we have resolved these in the design of the proposed definitive RCT.

7.2 Methodological issues in evaluating the health impact of welfare rights advice

Study design, level of randomisation, contamination and dilution

An appropriate trial design is required, preferably with both randomisation and concurrent controls. Individual level randomisation is preferable to cluster randomisation (e.g. at general practice level) as it requires a smaller sample size. The potential problem with individual level allocation is that there may be contamination between intervention and control participants in the same general practice. Where welfare rights advice is available from an open access service delivered in the general practice this is more likely to be the case. However, by using a welfare rights advisor (WRA) who only sees patients in their own homes, we found in our pilot RCT that contamination did not occur; not one control participant independently sought welfare rights advice during the period of follow-up, albeit this was only 6 months in this study.[11]

Equipoise and the control condition

A key consideration in designing the proposed trial was whether there is genuine equipoise. Welfare rights advice is known to increase access to financial and material resources in eligible clients. However, our systematic review of published and grey literature indicated that there is, as yet, no conclusive evidence that welfare rights advice leads to positive or negative changes in health.[28] We have discussed these findings with welfare rights advisors in the North East, with directors of adult social services, with a selection of GPs and with members of the public in our target age group. Each of these groups is in equipoise with regard to the proposed trial health outcomes. Having established this, we have also carefully considered the issue of study design and the ideal and feasible control conditions.

Ideally, controls should be adults as similar as possible to intervention group participants, but should not receive welfare rights advice, nor claim or receive new benefits, during the period of outcome follow-up. In medical trials, it is usual to withhold the intervention from the control group, because the health benefits of the intervention are not proven (i.e. clinical equipoise exists). Whilst this is the case with regard to the health impacts of welfare rights advice, as indicated above there is adequate evidence that welfare rights advice leads to significant financial and material gains for a proportion of recipients. Thus, it is considered ethically problematic to identify that control group participants are eligible to receive additional financial benefits, but either to keep this information from them, or to tell them of their eligibility but not give them advice or help with claims. To circumvent this dilemma, we propose that control participants do not receive a welfare rights assessment until the end of the trial period (i.e. following final outcome measurement). The full intervention (i.e. a full benefit assessment and active assistance with claims until resolved) will then be offered.

The proposed design will avoid unfairly raising expectations among controls. It will also help to avoid the potential problem of contamination, which could arise if control participants independently sought welfare advice (leading to dilution of the outcome effect), although we will not make any attempt to prevent this. The control condition is therefore, in effect, a 'wait-list' control, whereby the control group will wait to receive the intervention 24 months after the intervention group.

It is, of course, possible that some members of both intervention and control groups may die during the proposed 24 months follow-up period, and we would expect this in the course of any prospective study of this age group. In our pilot study, we recorded 7 deaths (4 intervention group, 3 control group) after 24 months follow-up.[11]

The proposed design of this RCT is fair because, at present, this kind of intervention is not routinely available to primary care patients and is generally only available to those who seek such services or are referred to them by a health or social care professional (e.g. a hospital social worker); these options remain open to patients in this trial. When targeted services are available in primary care, they tend to be short term and *ad hoc*. If we find any general practices in participating districts with access to such services they will be excluded from this trial. Genuine equipoise exists for the proposed health-related outcomes because participants will not be denied any entitlement that they would otherwise have received and, at present, the health impact of the proposed intervention is unknown.

The study design has been discussed with staff in each of the participating local authority social services departments. On the basis of these discussions, we believe that the welfare advisors are in equipoise about the intervention and have accepted the proposed study design. We will also ensure that the design is carefully explained to all participating staff during the staff training that will be delivered to welfare rights advisors. At these training sessions, we will specifically explore the issue of equipoise with the intervention staff to ensure that their position has not changed.

We recognise that there may be concerns as to whether the welfare rights advisors might feel tempted to offer benefits advice to controls before the two year 'wait period' has elapsed. This will not be possible for the simple reason that the welfare right advisors will not know the names of controls until a few weeks before their benefits assessment is due (i.e. two years after the their baseline assessment). Control participants' names will be held securely by the study team over this period.

Pragmatic versus explanatory

Not all participants in the intervention group will be eligible for additional benefits, and for those who are, they may receive variable amounts of financial and non-financial benefits. Ideally, we would wish to examine the health impact of receiving versus not receiving such benefits, as well as examining the potential for a gradient of effect ('dose-response' relationship) by amount of benefit received. However, to do so would require either an unethical design (see above) or a much larger sample size. In practice, the receipt of welfare rights advice is therefore the intervention we are evaluating (rather than receipt of specific benefits), as welfare rights advice is what is delivered as a service. The proposed trial is therefore a pragmatic (intention-to-treat) RCT of this complex intervention. Nevertheless, we will also assess the potential for exploratory sub-group

analyses looking at differential effects by participant characteristics (such as age and sex), receipt/non-receipt of, and levels of any benefits received. We anticipate that the trial will therefore contribute both to answering the question of whether the complex welfare rights advice intervention is effective in improving health and to providing new evidence on the theoretical question of whether increasing resources leads to better health.[13]

Length of follow-up

To enable accurate assessment of the health and social effects of welfare rights advice, an appropriate length of follow up is required. Experience from previous work suggests that considerable time may elapse between first advice session and receipt of new financial or material benefits. Often this is between 3 and 6 months, but can be longer if the case is not straightforward or if there is an appeal. For example, in our pilot RCT, 45% had received their entitlements by 3 months after their welfare assessment, 85% after 6 months, 95% after 9 months and 100% by 12 months.[11] Given such delays in receipt of benefits, as well as the fact that once received they need to be spent, it seems unlikely that they will have substantial impacts on health within the first 12 months. In our pilot, which was not adequately powered for substantive analyses, we found no suggestion of differences in health-related outcomes between intervention and control groups after 6, 12 or 24 months (although controls received the intervention after 6 months).[11] It is our view that the longer the delay between receipt of intervention and measurement of outcomes, the greater the chance of demonstrating a substantive effect on health.

To assess the acceptability of a range of delays in receiving the intervention among control group participants, we undertook an experiment in the context of a focus group discussion with a representative sample of low income, older people. To achieve this, simulations of the RCT randomisation procedures were undertaken. The first simulation concerned a typical drug trial and participants were given different coloured sweets depending on whether they were in the intervention or control groups. Then, randomisation for the proposed trial was simulated. The concept of equipoise, with regard to the health impacts of welfare rights advice was explained. Then, each group member was given an envelope from which they found out whether they were in the control group or the intervention group. If in the intervention group, they were allocated various types of benefit (e.g. Attendance Allowance + Council Tax Benefit + Housing Benefit) and the monetary value of these was revealed to them. We then talked the group through various time delays until the control group would also receive their welfare rights assessment and advice. The time delays we used were 3 months, 6 months, 9 months, 12 months, 18 months, 24 months, 36 months and 60 months. The initial response to the design was that it was unfair on the control group. However, when it was explained that: (i) while such services exist, they are not routinely targeted at or delivered to all people aged over 60, but only available on referral or demand; (ii) the findings of this study could influence the development of such services, involving collaboration between health and social services; and (iii) that a substantial 'wait' between intervention and control groups is needed to establish any differences in health outcome, the consensus of the group was that a delay of 24 months would be acceptable in the context of the proposed trial. We have, therefore, proposed a wait-list design for the proposed RCT, with a 24 month follow-up period for the main outcome assessment, followed immediately by delivery of the full intervention to the control group.

Selection bias

In our pilot RCT, GPs wrote to random samples of people aged over 60 years, inviting them to respond with an indication of their willingness to participate in the trial.[11] Using this method, 36% initially agreed to participate, 14% declined to participate and 50% failed to respond. Low levels of positive response to an 'opt in' approach carry risks of participation bias.[45 46] In their work on evaluating the impact of welfare rights advice for the Department of Work and Pensions,[47] Sainsbury and colleagues now routinely use an 'opt out' method of recruitment for similar populations (personal communication, Anne Corden, SPRU, York University, August 2010). We propose, subject to ethical approval, to use this type of recruitment method in this trial. This should significantly reduce the potential recruitment bias associated with 'opt in' recruitment methods and significantly increase the efficiency of trial recruitment.

Choice of outcome measures

Previously reported studies of the health effects of welfare rights advice have restricted reported health outcomes to general measures of health or psycho-social functioning (such as the SF36[38 39]) together with measurement of financial gains. In our earlier qualitative research among recipients of welfare rights advice, we identified a range of potential benefits of advice:[29 48]

Health (improvements in anxiety, depression, insomnia, reductions in medication or consultation, and health promoting changes in smoking, diet, physical activity, alcohol consumption)

Social (improvements in family or other relationships, increased ability to work, ability to care for relatives, etc.)

Financial (debt rescheduling and receipt of new benefits, e.g. Attendance Allowance, Disability Living Allowance, Mobility Allowance, Invalid Care Allowance, Incapacity Benefit, Housing Benefit, Income Support)

Material (e.g. access to free prescriptions, council tax exemption, entitlement to respite care, meals on wheels, re-housing or home modifications etc.)

The qualitative findings identified perceived benefits of the intervention in terms of:

- Increased affordability of necessities
- Increased capacity to manage unexpected future problems
- Decrease in stress related to financial worries
- Increased independence, including ability to travel, shop, visit GP etc.
- Increased ability to participate in family life and society

We undertook further qualitative work with study participants in our pilot RCT as well as collected planned outcome measures.[12] The pilot trial was not sufficiently powered for substantive analyses, but the feasibility of measurements was good, although the burden of measurement was overall felt to be relatively high but tolerated well by older people.

These findings, together with those from recent, similar research[47] point to the most significant health-related impacts of welfare rights advice being on quality of life, independence, social participation and mental health. There is no single, ideal outcome

measure that captures all of these domains, but the CASP19 instrument,[49 50] developed specifically with a view to measuring quality of life in older people, comes close and has been recommended by Corden et al as a composite measure of the impact of welfare rights advice.[47] It is a self-reported summative index, comprising 19 Likert scale items in 4 domains: control, autonomy, self-realisation and pleasure.[49] Its performance has been examined in several prospective studies, including the English Longitudinal Study of Ageing (ELSA).[51]

Generalisability

Our pilot trial was undertaken in one social services district (Newcastle upon Tyne) and in 4 general practice populations.[11] However, we know from other work and discussions locally that service delivery in welfare rights advice varies from area to area, as do general practice populations. It would, therefore, be of value if the intervention was delivered by welfare rights advice services in different social services districts, and evaluated in urban, semi-rural and rural general practice populations. To enhance the potential generalisability of the results, the proposed study will be undertaken across a range of geographical areas, social services departments and general practices.

We have discussed the proposed RCT with directors of adult social services in the North East region and gained their support. We have sought collaboration directly from all welfare rights advice services in the North East and, to date, have received pledges of support (including funding intervention delivery) from 10 district services. In our outline application, we anticipated 4, so this increase will help to spread the intervention load and increase generalisability further. We have also discussed the trial with the Primary Care Research Network, Northern and Yorkshire (PCRN-NY) and have its support. There are numerous willing practices in each local authority district and we do not envisage any difficulty with recruiting 2 practices per area into the trial.

It is possible, indeed likely, that the present welfare regime will change during the course of the trial. The proposed intervention is not dependent on any particular set of benefits and is adaptable to any new regime. This adds to its future generalisability.

Target Population

Although we recognise that isolated older people who are eligible for benefits may live in all areas, in order to maximise the efficiency (and impact) of welfare rights advice services provided through primary health care, the proposed RCT will focus on practice populations in socio-economically disadvantaged areas. Eligibility for health-related benefits (and failure to claim) increases with age and particularly post-retirement, although there are other key target groups such as single parents, non-claimants most likely to be accessed through primary care are predominantly in older age groups.[22 23 29 48] This trial will therefore focus on a predominantly post-retirement population (aged 60 years and over).

Nature of the intervention

The intervention to be delivered in the proposed trial is based on standard welfare rights advice services, of the type that can be found across all local authorities in England. Conventionally, however, these services are available only on demand or by referral. Thus, an older person admitted to hospital may be referred by a hospital social worker, doctor or nurse for benefits assessment prior to discharge. Only some services have undertaken targeting of welfare rights advice at a population level.[28] Those that have done so have found that there is a significant level of under claiming in the general population and in particular among older people.[25] The proposed intervention is therefore a modification of a standard welfare rights advice service to target proactively a particularly vulnerable population in which we know there are high levels of under claiming (i.e. over 60s in disadvantaged areas). The only reasonably reliable population registers in England at a local level are the primary care patient registration lists held by GPs and PCTs.

In our pilot work in Newcastle, we identified that efficiency and effectiveness (in terms of successful claims) could be maximised by making the service domiciliary, since a substantial proportion of over 60s have limited mobility and clients often need access to information kept at home during assessments.[29 52] Domiciliary visits also proved more popular with clients.+ We also found that welfare rights advisors need to provide 'active assistance' with claims, for example completing claim forms for clients, since this is a key barrier to claiming.[12 27] Lastly, GPs need to have appropriate awareness of welfare entitlements and, for health-related benefits in particular, an understanding of the medical criteria on which decisions are made so as to be able to support reasonable claims effectively in medical assessments requested by the benefits agency. Good communication between GPs and welfare rights advisors is essential to facilitate this. In our pilot trial, we delivered education and training on these issues to all GPs in participating practices.[11 12]

7.3 Benefits and risks

Benefits

Our systematic review of welfare rights advice services delivered in healthcare settings found that such interventions routinely result in financial and material benefits, but there was little evidence of measurable benefits for health or quality of life, primarily due to lack of rigorous outcome evaluations.[28]

Qualitative research, including our own studies, suggest that welfare rights advice has a positive impact on health-related quality of life, ability to maintain independence, social participation and mental health.[12 27-29 47] Delivery of welfare rights advice to older people, who would not normally receive such a service pro-actively, can therefore result in significant social, economic and potential health and quality of life benefits.

Risks

We are not aware of any major risks or harms associated with the delivery of such an intervention. However, it is possible that older people will spend additional resources in ways that are potentially harmful. These might include spending additional financial resources on alcohol or tobacco (with known risks for chronic diseases), on luxury' foods high in fat and sugar (e.g. chocolate) or on gambling which can be addictive and financially ruinous. It is also possible that increased independence and mobility (which we hypothesise will be associated with access to additional resources), could result in greater environmental exposures outside the home, resulting in infectious diseases or accidental injury. Furthermore, the intervention could lead to

greater use of car travel, resulting in lower levels of physical activity. However, we failed to find evidence of such risks in our pilot RCT or in previous published research and thus believe the risk of these outcomes is small and strongly outweighed by the potential benefits of additional income to those on low incomes and/or with chronic health conditions that qualify them for specific benefits. A number of these proposed outcomes are included in the proposed RCT.

Overall, it seems likely that people (and particularly older people) will spend the resources they have to access in non-harmful (or even healthful) ways and this is supported theoretically by the accumulated evidence on the strong social gradient in health associated with access to resources.[3 13] In addition, the welfare benefits to be promoted using our proposed intervention already exist and entitlement to them is enshrined in law, so to an extent we cannot assume responsibility for potential harms associated with them. Nevertheless, in this trial, we will assess potential adverse outcomes by: (a) identifying negative (unhealthy) changes in all primary and secondary outcome measures; (b) including additional, semi-structured open questions in follow-up questionnaires and interviews on other, potential, unanticipated outcomes in order to document these and develop explanations.

7.4 Rationale for current study

There is strong observational evidence of a relationship between access to resources and a range of health outcomes, which provides a theoretical basis for resource based interventions. Health inequalities are widening among older people. Welfare rights advice services to older people are widely delivered, and if targeted to those likely to have unclaimed entitlements (e.g. the most disadvantaged), can efficiently and effectively lead to a high yield of successful financial and non-financial benefit claims. No research to date has demonstrated whether providing welfare rights advice to older people can result in improved health.

We have already conducted a systematic review of welfare rights advice interventions linked to health services,[28] undertaken extensive qualitative research,[12 27 29 44 48] published a pilot RCT of a domiciliary welfare rights advice service for older people accessed via primary care,[11 12 44] extensively reviewed the methodological literature on appropriate design, methodology and outcome measures, and undertaken acceptability testing of the intervention and study design, and undertaken quantitative secondary analyses to support sample size estimation. We believe this provides the strongest possible platform for the proposed definitive RCT.

If the health benefits of this intervention are proven, targeted welfare rights advice services could be extended to ensure widespread provision for older people and other vulnerable groups, through collaboration between social services and primary care trusts or commissioners. The results of this trial may also have implications for the development of other resource-based interventions to tackle inequalities. This research is thus of fundamental, theoretical importance and has relevance for a range of government and health service policies.

8. Objectives

The proposed RCT and embedded economic and qualitative process evaluations aim to answer the following questions:

1. What are the effects on health-related quality of life of a domiciliary welfare rights advice service targeting independent living, socio-economically disadvantaged older people (aged ≥60 yrs)?
2. What are the cost consequences and what is the cost effectiveness of a domiciliary welfare rights advice service targeting independent living older people (aged ≥60 yrs)?
3. What is the acceptability to trial participants and relevant professionals of a domiciliary welfare rights advice service targeting independent living older people (aged ≥60 yrs)?
4. What are the unanticipated consequences (positive and negative) of a domiciliary welfare rights advice service targeting independent living older people (aged ≥60 yrs)?

9. Study Design

The study is a pragmatic, individual randomised, single blinded, wait-list controlled trial of welfare rights advice versus usual care, with embedded economic and qualitative process evaluations. The qualitative study will examine whether the intervention is delivered as intended, explore responses to the intervention and examine reasons for the trial findings, and explore feasibility of the translation of the intervention into routine policy and practice. The trial design is illustrated in the flow chart in Appendix 1, which has been drawn according to the CONSORT guidelines.[53]

9.1 Primary outcome measure

Quality of life, measured using the CASP 19 questionnaire.[49 50] CASP 19 will be administered by interview at baseline (pre-randomisation) and at follow-up 24 months post-randomisation, and by postal questionnaire at 12 months post-randomisation.

9.2 Secondary outcome measures:

The following secondary outcomes, based on the findings of previous research, including our own systematic review, qualitative study and pilot trial, [11 12 27-29 44 48] suggesting potential health-related outcomes of welfare rights advice, will be collected:

- *Health status*, measured by the EuroQoL (EQ5D)[55]
- *Functional ability* measured by the modified Townsend activities of daily living scale (The Medical Research Council Cognitive Function and Ageing Study. The description of activities of daily living in five centres in England and Wales. *Age Ageing* 1998;27:605-13)
- *Independence* measured by assessing living arrangements and carer status using the following categories: living independently or with carer support, in own home, with relations, care home or hospital
- *Mental health* measured by the PHQ-9 depression questionnaire[56-58]
- *Health-related behaviours* assessed by self-report to measure change in key indicator behaviours, such as smoking, alcohol consumption, diet (consumption of key food groups) and physical activity, as in our pilot RCT[11]
- *Mortality* assessed by identifying deaths at 12m and 24m from GP records (we will do this prior to commencing follow-up assessments, so as not to attempt to contact the recently deceased, which may cause distress to bereaved relations)
- *Social support and participation* measured by the Social Support Questionnaire.[59]
- *Perceived financial wellbeing* measured by the Affordability Index
- *Fuel poverty* measured using the National Energy Action (NEA) definition (where a household can achieve temperatures needed to maintain health and comfort for expenditure of less than 10% of income)[60]
- *Financial status* measured by a standard assessment tool used in our pilot RCT.[11] Includes data on all sources of household income, including benefits, major outgoings (rent/mortgage, fuel bills etc.), debts and capital assets (i.e. home and savings). As well as these data, at follow-up detailed data will be collected on new benefits received since baseline, including one-off (lump sum) payments and regular, weekly or monthly income.
- *Material (dis)advantage* measured through standard questions to ascertain home ownership, size of home (number of 'living' rooms), car ownership, and access to household amenities (such as central heating, cooker, fridge, freezer, etc.).
- *Demographic factors* including age, sex, ethnicity, marital status and living arrangements, including dependants.

These outcomes will be assessed by structured, face-to-face interview at baseline (pre-randomisation) and 24 months post-randomisation.

9.3 Other quantitative data to be collected

Data will also be collected to assess the costs of the intervention, from public sector and treasury perspectives (see 'economic analysis' below). The service costs of delivering the intervention will be assessed by collecting data on staff salaries from all participating services, as well as data on typical caseloads. WRAs routinely record information on visits to clients and we will use these data to estimate time spent with study clients, as well as travel costs. These data will be used to derive an average cost per case of delivering the intervention to our intervention group participants, as in our pilot RCT.[11] To assess the treasury perspective, total gains in financial benefits for all intervention clients will be provided by WRAs. We will also estimate the cost to the treasury of non-financial benefits based on details of successful claims provided by WRAs. These costs will then be summed to derive average costs to the treasury per case for all intervention participants.

9.4 Definition of end of trial:

The end of trial will be the last participant's final study contact, for 24 months' post-randomisation follow up. Following the end of the trial, individuals randomised to the control group will be offered the welfare rights advice intervention.

10. Study Population

10.1 Randomised Controlled Trial

10.1.1. Inclusion criteria – general practices

GP populations in disadvantaged areas of North East England, including urban, rural and semi-rural areas, with no previous access to targeted welfare rights advice services delivered to primary care patients, will be included. All practices from participating social service districts will be ranked according to deprivation score (Index of Multiple Deprivation calculated at Middle Super output Area level for practice postcodes, according to the method of Griffin et al[54]). Those practices in the lower two fifths of the deprivation ranking distribution without existing dedicated or targeted will be eligible for inclusion.

10.1.2. Inclusion Criteria - patients

- Volunteer men and women registered with a General Practice in one of 9 social services areas (1 individual per household)
- Aged 60 years and over
- Providing informed consent

10.1.3. Exclusion criteria - patients

- Patients resident in nursing homes or hospitals at the time of identification
- Diagnosed terminal illness
- By virtue of current physical/mental health cannot participate in the research
- Lack of fluency in written and spoken English

10.2 Qualitative study

A range of professionals involved in service commissioning, policy and strategy will be interviewed including i) public health/NHS (GP consortia); ii) social and welfare rights services; iii) Pension Service, Department for Work and Pensions; and (iv) the voluntary sector (see further details in section 11.4).

11. Screening, Recruitment, Consent and Randomisation

11.1 Identification and screening of trial participants

We will recruit practices with the help of the PCRN-NY. The study will take place in 10 local authority districts (Stockton, Darlington, Middlesbrough, County Durham, Sunderland, South Tyneside, North Tyneside, Newcastle, Gateshead, Northumberland) in which social services departments have agreed to provide welfare rights advice services. We plan to recruit 2 general practices per social services district. Potentially eligible practices – those in the lower two fifths of the deprivation ranking distribution – will be identified as described in Section 10.3 above. We will then liaise with Welfare Rights Services to establish whether any of these practices have existing dedicated or targeted welfare rights advice services, since this will render them ineligible. Next, we will ask the PCRN to identify which of the practices still eligible have indicated willingness to participate in research. If more than 2 general practices from each list have expressed willingness to participate in research, we will order the remaining practices randomly and then contact then sequentially until 2 practices from each social services district have agreed to participate in the trial.

General practices in North East England have access (via PCRN-NY and the Comprehensive Local Research Networks (CLRNs)) to personnel and financial resources to identify and approach research study participants. Using PCRN-NY and CLRN personnel and financial resources, each participating practice will be asked to generate a random sample of up to 300 people aged 60 and over from their practice register. Practice staff will scrutinise their list to identify any patients known to be resident in hospital or long-term care, who will be excluded (see Section 10.2 above). They will also check to ensure that only one person per household has been selected for this list. If 2 or more people from the same address are found, one will be selected at random to be retained and the other(s) removed from the sample list.

11.2 Recruitment

This list of up to 300 names per practice will be randomly ordered and the first 100 patients on the list will be sent a letter and study information sheet by their GP, inviting participation in the trial. The letter will explain that, unless the participant objects (by returning an opt-out slip to the practice within 2 weeks), their name and contact details will be passed to the research team, who will then contact them directly to discuss the trial further and seek informed consent.

After two weeks, contact details of those who have not opted out will be passed to the research team. Research staff will contact these individuals and, if acceptable, arrange a face-to-face meeting at a mutually convenient time in the participant's own home or another location of the participants choosing.

Our target for recruitment from each practice will be predetermined (depending on the number of practices involved) in order to achieve the total sample. If this number is not achieved from the first 100 mailed, subsequent mailings of further names from the list of up to 300 will take place until the required number have been recruited. The number to be included in subsequent mailings will be determined by the number of responses already received. Since recruitment interviews will be spread over a 6 month period, this iterative recruitment process should not delay overall recruitment.

11.3 Consent

At the initial appointment (Section 11.2), the research interviewer will first seek written, informed consent and then, if appropriate, proceed to collect baseline data. Interviewers will communicate in English and if English is not the first language of any participant and (s)he is unable to speak fluently, the participant will be excluded from the study. Friends, relations or carers will not be used as interpreters and interpreting services available to WRAs from local authorities will not be available for research interviews (the CASP19 has not been translated to other languages nor cross-culturally validated).

The researcher will assess if an individual has the capacity to consent. If it is established that an individual is unable to provide written consent because of literacy, vision or motor problems, it will be arranged for verbal consent to be taken in the presence of an independent witness (e.g. family member) who will initial, sign and date the consent form on the participant's behalf.

Although unlikely to be a frequent occurrence, it is conceivable that a participant may lose mental capacity *during* the follow up period. We will ensure that any information or material relating to the participant provided prior to the loss of capacity is of a prescribed description, having been obtained before the participant's loss of capacity. Furthermore, the investigator and research interviewers will undertake all reasonable steps for the purpose of protecting the study participant. In accordance with the Mental Capacity Act 2005, nothing will be done to the person to which he or she appears to object (whether by showing signs of resistance or otherwise) except where what is being done is intended to protect him or her from harm or to reduce or prevent pain or discomfort.

11.4 Identification and recruitment of participants for qualitative sub-study

Interviews with 30 purposively sampled trial participants will take place between 8-11 months and between 20-23 months (approximately 15 interviews in each period). Trial participants will be identified through the trial database and recruited to achieve a maximum variation sample with respect to group allocation, gender, age, benefit entitlements and any unanticipated consequences of the intervention identified at 12 month follow-up.

A sample of 10 professionals/stakeholders will also be interviewed at 20-23 months. Stakeholders will include representatives of the Department for Work and Pensions, Benefits Agency, adult social services managers, welfare rights advisors, GPs, primary care commissioners and directors of public health.

Participants will be asked during baseline assessment and consent procedures if they would be willing to participate in the qualitative interviews. Those selected for interview (trial participants and professionals/stakeholders) will be sent a letter of invitation and Participant Information Sheet by the research team. Contact details for the researchers will be provided so that those approached to participate can ask any questions they may have before coming to a decision on participation. Separate

informed consent will be taken for the interviews and lack of consent to participate in this element of the research will not prevent trial participants from continuing in the trial.

Sampling and interviews with both groups will continue until data saturation is achieved.[61]

12. Study Intervention Details

12.1 Intervention

Welfare rights advice consultations and active assistance with benefit claims will be offered and delivered in participants' own homes, tailored to individual needs by a trained WRA employed by adult social services departments in North East England, Following randomisation, intervention group participants will be given an appointment in their own home with a WRA within 2 weeks, during which participants will undergo a full benefit entitlement assessment involving: assessment of financial, material and welfare status; assessment of previous benefit entitlement and claims; discussion of current entitlement and options for action, including new claims (financial and non-financial). Active assistance with benefit claims and other welfare issues will be given. Complex claims or those referred for further assessment or tribunal will be managed in the usual way by WRAs. Participants will be followed up intermittently by WRAs until they no longer require assistance (cases are usually 'closed' once all claims and appeals have been resolved satisfactorily). It is expected most claims will be resolved with 3 months, but some may take up to 12 months.[11] The intervention will be funded and provided by social services departments in 9 local authority areas across the North East by WRAs.

North East Strategic Health Authority has provided funding for training of WRAs to ensure a consistent approach to delivery of the intervention, and for training of GPs to ensure consistent approaches to medical assessments related to relevant claims. Such training was delivered in the context of our pilot RCT[11 12] and we have the agreement of Newcastle Social Services Department, Welfare Rights Service, to provide similar training for this trial.

12.2 Comparator (control condition)

Participants randomised to the control group will receive 'usual care' from both health and social services after randomisation until they have completed their 24-month follow-up assessment. They will be given no advice regarding welfare rights as a part of the study intervention during this period. However, they may independently seek welfare rights advice from social services or from charity or voluntary sector organisations. If this occurs, they will remain in the trial, but details of such advice and ensuing claims and outcomes will be recorded at the 24 months follow-up assessment. Following their 24-month follow-up assessment, they will receive the intervention, as delivered to the intervention group, including all follow-up visits by WRAs and assistance with claims and appeals over the following months, until all claims have been resolved.

12.3 Long-term care

Both intervention and control group participants will remain clients of the welfare advice service beyond the end of the trial if necessary, until such time as their help is no longer needed, as per usual social services protocols.

13. Randomisation

Following baseline measurements (see Section 11.3 above), participants will be randomised in a 1:1 ratio to intervention or control condition. Research interviewers will notify the project secretary after each baseline interview that a new participant has been successfully recruited. The secretary will hold sequential allocation tables for each practice, independently generated from random numbers prior to recruitment. The secretary will allocate all participants to intervention or control group in the sequence that they are recruited and immediately send each participant a standard letter informing them of their group allocation. The secretary will also immediately inform the appropriate WRA of the contact details of each newly allocated participant and indicate whether they are to be seen within 2 weeks (intervention) or in 24 months (controls). The research interviewers will not be notified of allocation status to ensure that they remind blinded for the duration of the study.

14. Study Data

14.1 Assessments / Data Collection

Baseline assessment (pre-randomisation)

Baseline data collection will be by means of a structured face-to-face interview in the participant's home or at another venue of the participant's choice. Following provision of informed consent, the following data will be collected (see Sections 9.1 – 9.3 for details of instruments):

- Quality of life (CASP 19)
- Health status (EQ5D)
- Functional ability (modified Townsend activities of daily living scale)
- Independence measured by assessing living arrangements and carer status using the following categories: living independently or with carer support, in own home or with relations
- Mental health (PHQ-9)
- Health-related behaviours
- Social support and participation (Social Support Questionnaire)
- Perceived financial wellbeing (Affordability Index)
- Financial status (standard assessment tool from pilot)
- Fuel poverty measured using the National Energy Action (NEA) definition (where a household can achieve temperatures needed to maintain health and comfort for expenditure of less than 10% of income)
- Material (dis)advantage measured through standard questions to ascertain home ownership, size of home (number of 'living' rooms), car ownership, and access to household amenities (such as central heating, cooker, fridge, freezer, etc.).
- Demographic factors including age, sex, ethnicity, marital status and living arrangements, including dependants.

12-month follow-up

Mortality status will be assessed from GP records at 12 months post-randomisation. Practices will be sent a list of participants and asked to check status. We will also do this prior to commencing follow-up assessments, so as not to attempt to contact the recently deceased, which may cause distress to bereaved relations

A postal questionnaire will be used to capture CASP 19 data at 12 months post-randomisation. Two reminders will be sent, a letter at 2 weeks and a letter and questionnaire at 4 weeks. Data will be included if returned within 1 month on the second reminder.

24-month follow-up

Mortality status will be assessed from GP records at 24 months post-randomisation. Practices will be sent a list of participants and asked to check status. We will do this prior to commencing follow-up assessments, so as not to attempt to contact the recently deceased, which may cause distress to bereaved relations

24-month follow-up data collection from participants will be by means of a structured face-to-face interview in the participant's home or at another venue of the participant's choice. Following provision of informed consent, the following data will be collected (see Sections 9.1 – 9.3 for details of instruments):

- Quality of life (CASP 19)
- Health status (EQ5D)
- Functional ability (modified Townsend activities of daily living scale)
- Independence measured by assessing living arrangements and carer status using the following categories: living independently or with carer support, in own home, with relations, care home or hospital
- Mental health (PHQ-9)
- Health-related behaviours
- Social support and participation (Social Support Questionnaire)
- Perceived financial wellbeing (Affordability Index)
- Financial status (standard assessment tool from pilot)
- Fuel poverty measured using the National Energy Action (NEA) definition (where a household can achieve temperatures needed to maintain health and comfort for expenditure of less than 10% of income)

- Material (dis)advantage measured through standard questions to ascertain home ownership, size of home (number of 'living' rooms), car ownership, and access to household amenities (such as central heating, cooker, fridge, freezer, etc.).
- Demographic factors including age, sex, ethnicity, marital status and living arrangements, including dependants.

Dates of commencement of new benefits will be ascertained, including non-financial (material) benefits, such as aids and adaptations to the home (e.g. stair rails, ramps, disabled car sticker (blue badge), home insulation, etc.) by WRA on an ongoing basis.

14.2 Qualitative Data Collection

Semi-structured interviews will be undertaken in 2 phases. Interviews with 30 purposively sampled participants will take place between 8-11 months and between 20-23 months (approximately 15 interviews in each period). A sample of professionals/stakeholders (including those from all key groups involved: WRAs, GPs, primary care and social services commissioners, directors of public health, benefits agency and Department for Work and Pensions officers) will also be interviewed at 20-23 months

Interviews with trial participants will explore: acceptability of the intervention and research design; unanticipated consequences of the intervention; and perceived benefits of the intervention. Interviews with stakeholders will explore: acceptability of the intervention, training and research; fidelity of the intervention; and likely implications of the intervention for translation into routine policy and practice, both within the North East and more widely.

14.3 Data Handling & Record Keeping

Study data will be entered directly into a secure Access databases during interviews for processing and management, and a record of any changes made to the data post-entry will be maintained. All personal information obtained for the study will be held securely at the trial sites and will be treated as strictly confidential. Twelve month data in the form of self-completion questionnaires will outsourced to a data entry company.

Data collection and transfer in this study will comply with NRES and Caldicott guidelines and the Data Protection Act (1998). All patients will be allocated a unique study identifier, which will be used on all data collection forms and questionnaires to preserve confidentiality; names or addresses will not appear on completed questionnaires or other data collection forms. Only a limited number of members of the research team will be able to link the unique identifier to patient-identifiable details (name, address and telephone number) which will be held on a password-protected database. All study documentation will be held in secure offices, not open to the public and all members of the research team with access to identifiable or anonymised data will operate to a signed code of confidentiality. Transmission of original or hard copy records (e.g. questionnaires, interview recordings) will be by secure fax, post or hand delivery by members of the research team or by the WRAs. Participants will be informed in the patient information sheet about the transfer of information to IHS and about levels of access to patient identifiable data, and will be asked to consent to this. Any data used in publications from Do-Well will be fully anonymised; it will not be possible to identify individual patients from such publications.

At the end of the study, original questionnaires, interview transcripts and consent forms will be securely archived for 15 years following publication of the last paper or report from the study, in line with Sponsor policy and NCTU standard operating procedures. This will also allow any queries or concerns about the data, conduct or conclusions of the study to be resolved. Both sets of data will be archived after 5 years. Anonymised qualitative data will be submitted to the Qualdata archive.

14.4 Sample Size

Trial sample size and power

A minimum total of 750 participants will be randomised to intervention and control arms, providing 90% power at 5% significance level to detect a 1.5 unit difference in mean CASP19 score[49 50] between intervention and control groups, assuming a standard deviation of 8.7 and a correlation between baseline and 24 months of 0.74,[51] and 15% attrition over 24 months (as experienced in our pilot RCT)[11] (see Appendix 1, Flow Chart). There has been no published work to establish a meaningful or clinically important difference on the CASP19 scale. However, we have used data from two waves of the English Longitudinal Study of Ageing in those aged ≥60 yrs to investigate the adjusted mean difference in CASP at Wave 2 between groups whose social or health circumstances had changed. Examples of changes in CASP19 score associated with changes in health or social circumstances that we might expect to see in the proposed trial include: 'developed limiting illness' -2.8 units; 'developed depression' -2.7units; 'lost access to car' -1.8 units; 'increased chance will not meet financial needs' -1.1 units. These differences on the CASP19 scale suggest that a difference of 1.5 units would represent a 'clinically' important difference.

Our sample size should also provide power to demonstrate some clinically significant differences in secondary outcomes. For example, 750 participants will provide 90% power to detect a difference between a prevalence of 11% and 4% of clinically significant depressive symptoms (PHQ-9 score ≥10).

Qualitative sub-study sample size

Sample size for the qualitative sub-study will be determined by data saturation. We anticipate that up to 30 trial participants and up to 10 stakeholders will be included.

14.5 Statistical Analyses

Analyses of covariance and regression methods will compare primary and secondary outcomes between interventions and controls at 24 months, adjusting for baseline outcome values and any imbalance in other covariates as appropriate.

Analyses will be by intention-to-treat. It will be necessary to consider any difference in attrition rates, and the non-randomness of the attrition, when comparing quality of life between the two groups. In the pilot RCT only 7/126 (5.5%) died during the 24 month follow-up, so it is thought unlikely that methods for joint modelling of survival and longitudinal data will be necessary.

Exploratory sub-group analyses will also be undertaken, for example to examine differences in outcome between men and women, by age and by amount and type of benefits received.

14.6 Health Economic Analyses

The economic evaluation will consist of a cost analysis conducted from the perspectives of public sector services ('Do-Well' service delivery costs, see Section 9.3 above), and that of the Treasury (total cost of additional benefits paid out). The mean change in benefits and the mean change in total income of participants will also be calculated.

The cost analyses above will be used in conjunction with study outcomes to produce a cost consequences analysis. If any significant change in EQ-5D health utility scores can be attributed to the intervention, we will present a cost-utility analysis. The assumptions that underpin any such cost-utility analysis will be subjected to one-way sensitivity analysis and, in addition, extensive probabilistic sensitivity analysis will be used with results presented in the form of cost-effectiveness acceptability curves.

14.7 Qualitative Analyses

All interviews will be digitally recorded (with permission) and transcribed verbatim. Data will analysed thematically following the Framework method[62] with constant comparison[63] and deviant case analysis[64] to enhance validity.

15. Compliance and Withdrawal

15.1 Assessment of Intervention Fidelity

All participating welfare rights advisors will be trained prior to intervention delivery on the study and the procedures for delivering welfare rights advice and following up actions (benefit claims) in a standardised manner. A standardised checklist will be developed that will document the benefits applied for and the result of the application with dates. The RA will closely monitor the checklists and maintain regular contact with all WRAs. Each WRA will be observed at least once with a randomly chosen participant in order to ensure a standardised intervention delivery.

15.2 Withdrawal of participants

Participants have the right to withdraw from the study at any time for any reason, and without giving a reason. It is understood by all concerned that an excessive rate of withdrawals can render the study uninterpretable; therefore, unnecessary withdrawal of patients should be avoided. Should a patient decide to withdraw from the study, all efforts will be made to report the reason for withdrawal as thoroughly as possible.

There are two withdrawal options:

1. Withdrawing completely (i.e. withdrawal from both the study intervention and provision of follow-up data)
2. Withdrawing partially (i.e. withdrawal from study intervention but continuing to provide follow-up data by completing questionnaires and interviews).

Consent will be sought from participants choosing option 1 to retain data collected up to the point of withdrawal. Participants will be asked if they would be happy for the reason for the decision to withdraw to be recorded.

16. Data Monitoring, Quality Control and Quality Assurance

16.1 Discontinuation rules

Discontinuation on safety grounds is not anticipated. Interim analyses of effectiveness are not planned, and therefore discontinuation for reasons of futility or superiority is not anticipated. At the request of the funding body, early stopping rules for (lack of) feasibility are in place.

1. Recruitment will be reviewed in month 7 of the project, which is the 3 month (mid-) point of the recruitment period, at which we anticipate reaching a target of 325 participants recruited.
2. If recruitment is 100% or more of predicted at this point, the project will continue as planned
3. If recruitment of GP practices or individual participants at this point is less than 50% of that predicted, it is unlikely that the project can complete within a reasonable time and budget and baring exceptional circumstances will close. However, if it can be convincingly demonstrated that the project is still viable, the process set out in (4) will be followed.
4. If recruitment falls between these measures, the project team will prepare a report detailing how recruitment will be addressed and what the time and budget implications will be, and how much extra resource will need to be met by the PHR programme. The programme will then use its usual procedures to reassess the value for money of the project and take a view on extending funding as required.

16.2 Monitoring, quality control and assurance

The study will be managed through the Institute of Health and Society, with the input of the UKCRC registered Newcastle Clinical Trials Unit. Quality control will be maintained through adherence to this study protocol, NCTU SOPs, the principles of GCP and the Research Governance Framework for Health and Social Care Research.

The Study Management Group will comprise co-applicants, project secretary, researchers, trial manager and database manager and will meet monthly. Day to day responsibility for project management will be taken by Dr Katie Lock. The study will be conducted under the auspices of Fuse, the Centre for Translational Research in Public Health (www.fuse.ac.uk), a UKCRC Public Health Research Centre of Excellence.

Sponsorship

North Tyneside Primary Care Trust will be sponsor for the research.

The study may be subject to inspection and audit, on a routine basis or 'for cause', by representatives of North Tyneside Primary Care Trust under their remit as sponsor. The investigator(s) will permit trial-related monitoring, audits, and REC review, providing direct access to source data/documents.

Independent Trial Steering Committee (ITSC)

An Independent Trial Steering Committee (ITSC) will provide overall supervision of the trial.

The ITSC will comprise: Professor Stephen Walters, Professor of Medical Statistics and Clinical Trials, ScHARR, The University of Sheffield; Professor Colin Green, Associate Professor in Health Economics and Head of Health Economics Group, Peninsula Medical School, Exeter University; Nick Whitton, Head of commissioning for adult services, Adult and Community Services, Durham County Council; Sally West, Strategy Adviser - Income and Poverty; Age UK; Ann Cordon, Senior Research Fellow, Social Policy Research Unit, The University of York; Alistair Chisholm, Manager - Face to Face debt advice, Newcastle Citizens Advice Bureau along with Professor Martin White (Chief Investigator), the study statistician (Ms Denise Howel) and project manager (Dr Katie Lock). Observers from the NIHR PHR programme will be invited to all ITSC meetings.

Following the initial pre-study meeting, the ITSC will meet annually. Its role is to monitor progress and supervise the trial to ensure it is conducted to high standards in accordance with the protocol, the principles of GCP, relevant regulations & guidelines and with regard to participant safety and wellbeing. A written charter will be agreed and used by the TSC.

Data Monitoring & Ethics Committee (DMEC)

This is a low risk trial and major safety data are not anticipated; therefore a Data Monitoring & Ethics Committee (DMEC) will not be convened.

Public engagement

We have engaged with service users from the outset in designing this study and will continue to do so throughout its lifetime. The proposed research design was discussed with a representative sample of low income, older people, and they support it. These members of the public have provided valuable insight and advice regarding study design and patient-relevant end-points at the outline stage. The Do-Well trial will have strong links with Patient and Public Involvement networks in England and Wales, and we will capitalise on these links to discuss key study aspects with lay members of the respective local steering committees/patient & public involvement groups. A key point of reference will be the Public Involvement and Engagement Committee (PIEC) of Fuse, which has been convened to provide public input to research studies within the Centre. PIEC has close links with INVOLVE, the national advisory group that supports greater public involvement in NHS, public health and social care research. Through these interactions, direct patient/carer involvement will support:

- Recruitment and consent – for example, contribution to the development of suitable letters of invitation to participate, participant information sheets etc

- Data gathering – through developing patient information materials and covering letters, explaining the study instruments
- Interpretation of findings – through the development of recommendations for practice and patient information leaflets
- Dissemination of the findings through existing networks (i.e. patient support groups, society branches and UK clinical research networks).

In addition, we will hold a public engagement event towards the end of the project to disseminate our findings. This will be organised with support from Voice North, a panel of over 3000 older people in the North East established by the Institute for Ageing and Health.

Stakeholder engagement

The study will be supported by the Northumberland, Tyne & Wear and County Durham & Tees Valley CLRNs and the PCRN-NY (Director: Dr Scott Wilkes), which will facilitate access to general practices and secure service support costs to enable recruitment from primary care. The study is supported by the NHS and North East SHA has provided funding for training of WRAs and GPs. We have also discussed the study with representatives of Age UK, the Benefits Agency and Department for Work and Pensions, who have indicated their support. Directors of adult social services in the North East support the study and to date 9 social services departments have pledged to fund and deliver the trial interventions via their welfare rights advice services.

Members of these key stakeholder organisations will be represented on our ITSC. We will also engage stakeholders regionally and nationally, once we have results from the study by preparing a policy briefing, presenting the findings at policy-related events or conferences and in policy publications.

17. Adverse event reporting

For the purposes of this study no reporting of serious adverse events is required. All adverse events will be managed as per normal care, since the intervention process of this study does not deviate from normal care.

18. Ethics & Regulatory Issues

The conduct of this study will be in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

Favourable ethical opinion from an appropriate REC and R&D approval from the PCTs in which the participating general practices are situated will be sought prior to commencement of the study. The general practices in this study will be acting as Participant Identification Centres (PICs) rather than research sites. Nonetheless, local approvals will be sought before recruitment may commence at each site. The research team will require a written copy of local approval documentation before any practice can commence participant identification and contact.

Information sheets will be provided to all eligible participants and written informed consent obtained prior to any study-specific data collection or intervention procedures. All study participants will have the capacity to provide consent on their own behalf. For participants who have the capacity to provide informed consent for themselves but cannot sign the consent form because of literacy, vision or motor problems, verbal informed consent will be taken in the presence of an appropriate independent witness who will sign and date the consent form on the participant's behalf. In the unlikely event that a participant loses mental capacity *during* the follow up period, we will ensure that any information or material relating to the participant provided prior to the loss of capacity is of a prescribed description, having been obtained before the participant's loss of capacity. Furthermore, the investigator and research interviewers will undertake all reasonable steps for the purpose of protecting the study participant. In accordance with the Mental Capacity Act 2005, nothing will be done to the person to which he or she appears to object (whether by showing signs of resistance or otherwise) except where what is being done is intended to protect him or her from harm or to reduce or prevent pain or discomfort.

19. Confidentiality

Personal data will be regarded as strictly confidential. To preserve anonymity, any data collection forms, questionnaires and interview transcripts will identify participants by a unique study identification code only. Only a limited number of individuals will be able to link this identifier to patient-identifiable data (names, addresses and other contact details required to arrange visits by the WRAs, research interviews, and to send out questionnaires and (where relevant) invitations to take part in the qualitative sub-study). These patient-identifiable data will be held on a password-protected database. All names and other details which might allow an individual to be identified from interview transcripts will be removed following transcription and checking of the interview data.

Data collection and transfer in this study will comply with NRES and Caldicott guidelines and the Data Protection Act (1998). All study documentation will be held in secure offices, not open to the public and all members of the research team with access to identifiable or anonymised data will operate to a signed code of confidentiality. Transmission of data and records (e.g. questionnaires, interview recordings) between general practices, participants' homes and the Institute of Health and Society will be by recorded postal delivery. Participants will be informed in the patient information sheet about the transfer of information to the NCTU and about levels of access to patient identifiable data, and will be asked to consent to this.

Study data will be entered from source data (e.g. questionnaires) into secure databases for processing and management, and a record of any changes made to the data post-entry will be maintained.

Any data used in publications from Do-Well will be fully anonymised; it will not be possible to identify individual patients from such publications.

20. Insurance and Finance

NHS North of Tyne is the Sponsor for this study. Indemnity in respect of potential liability arising from negligent harm related to study management will be provided by Newcastle University schemes. Indemnity in respect of potential liability arising from negligent harm related to study design is provided by Newcastle University Insurance schemes for those protocol authors who have their substantive contract of employment with the University and by NHS schemes for those authors with an NHS organisation. Indemnity for WRAs will be provided by their employer. This is a non-commercial study and there are no arrangements for non-negligent compensation.

The study is funded by the NIHR Public Health Research Programme.

The North East SHA has provided funding for training of WRAs and GPs.

The study will be supported by the Northumberland, Tyne & Wear and County Durham & Tees Valley CLRNs and the PCRN-NY (Director: Dr Scott Wilkes), through which we will secure NHS service support costs to enable recruitment from primary care.

21. Study Report / Publications

The data will be the property of the Chief Investigator and Co-Investigators. Publication will be the responsibility of the Chief Investigator and published under the authorship agreed with the Co-Investigators. Drafts of all proposed publications will be submitted to NIHR Public Health Research as the funders 28 days prior to submission in line with contractual obligations.

We will seek to publish the trial protocol during the first 6 months of the study in an open-access journal. We will seek to publish the main trial, exploratory analyses, economic analyses and qualitative findings in high impact, publically accessible academic journals, during the final 6 months of the project. We will also seek dissemination via national (e.g. Society for Social Medicine, British Sociological Association, UK Public Health Association) and international (e.g. International Society for Equity in Health, European Public Health Association) conferences.

Results of the study will also be reported to the Sponsor and Funder, and will be available on their web sites as well as Fuse and IHS websites.

Participants will be informed about the findings of the research at the end of the study, and will be offered a lay summary of the results.

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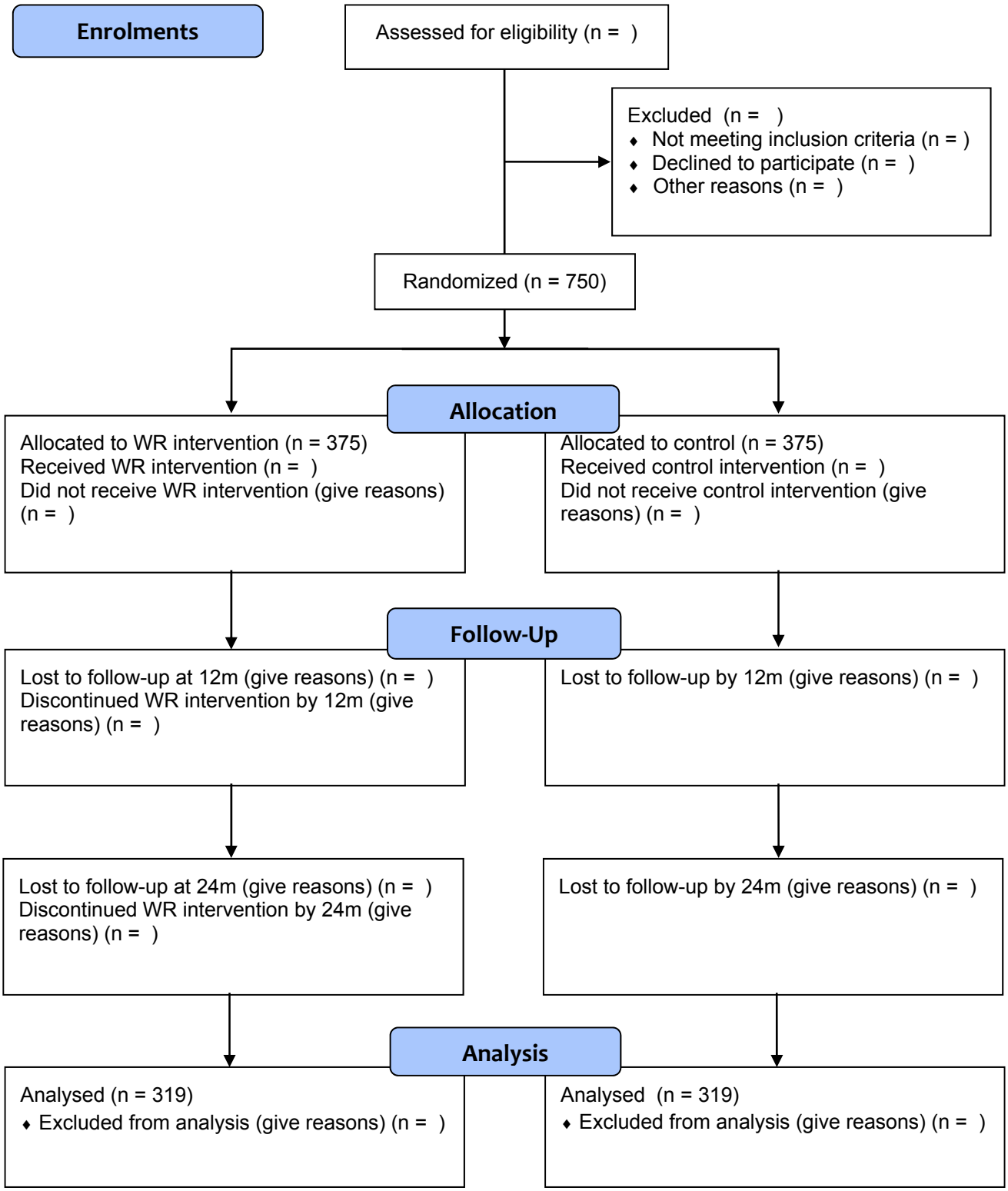
Appendix 1 - CONSORT 2010 standard RCT flow diagram

(numbers, where they appear, are estimates at this stage)



Appendix 1: Figure 2: Do-Well RCT – project timeline and milestones

Anticipated dates	01/06/11	01/07/11	01/08/11	01/09/11	01/10/11	01/11/11	01/12/11	01/01/12	01/02/12	01/03/12	01/04/12	01/05/12	01/06/12	01/07/12	01/08/12	01/09/12	01/10/12	01/11/12	01/12/12	01/01/13	01/02/13	01/03/13	01/04/13	01/05/13	01/06/13	01/07/13	01/08/13	01/09/13	01/10/13	01/11/13	01/12/13	01/01/14	01/02/14	01/03/14	01/04/14	01/05/14	01/06/14	01/07/14	01/08/14	01/09/14	01/10/14	01/11/14	01/12/14	01/01/15	01/02/15	01/03/15	01/04/15	01/05/15	01/06/15
Project month	-6	-5	-4	-3	-2	-1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43
Ethics approval						1																																										
Staff recruitment						2																																										
Preparation and finalisation of materials						3																																										
Recruitment of practices									4																																							
Training of GPs and WRAs									5,6																																							
Participant recruitment*															8																																	
Intervention delivery															9												13																			21			
Qualitative fieldwork & analysis																				11				12								16				18												
Participant follow-up (12m, 24m)																											14												19									
Quantitative data preparation																	10												15													20						
Trial data analyses																																17												22				
Dissemination, public engagement, contingency									7				27						27						27						27					27								27	23	24	25	26		28
Trial Steering Committee meetings																																																

*Recruitment rate will be 30 participants/week over 25 weeks across 18 general practices in 9 local authority areas, served by 9 WRAs and 4 research interviewers (~2 patients/ general practice/week, ~4 patients/WRA service/week).

Mile stones:

1. Ethical approval obtained
2. Research and admin staff recruited and in post
3. Study materials finalised (e.g. questionnaires, letters, interview schedules)
4. 18 general practices recruited
5. Training delivered to WRAs
6. Training delivered to GPs in 18 practices
7. Protocol paper submitted to open access journal
8. 750 participants recruited and randomised
9. All intervention group participants received initial assessment and advice from WRA
10. All baseline data cleaned and prepared for analysis
11. First phase of qualitative interviews completed
12. Preliminary analysis of first phase qualitative interviews completed
13. All intervention group WRA casework resolved by WRAs
14. 12m follow-up postal questionnaire survey completed
15. 12m Questionnaire survey data entered, cleaned and prepared for analysis
16. Second Phase of qualitative interviews completed
17. Analysis of 12m data completed to identify unanticipated or adverse consequences of intervention
18. Preliminary analysis of second phase qualitative interviews completed
19. 24m follow-up interviews completed
20. 24m follow-up data cleaned and prepared for analysis
21. All control group participants received initial assessment and advice from WRA (ongoing casework to be completed beyond end of study)
22. All statistical, economic and definitive qualitative analyses completed
23. Lay summary of findings sent to participants
24. Policy briefing prepared
25. Stakeholder dissemination and engagement event held
26. Papers on main outcomes drafted and submitted to journals
27. Progress reports to NIHR
28. Final report to NIHR
29. Independent Trial Steering Committee Meetings *(dates to be added*

This protocol refers to independent research commissioned by the National Institute for Health Research (NIHR). Any views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NHS, the NIHR,
the PHR programme or the Department of Health.