Randomised controlled trial with economic and process evaluations of domiciliary welfare rights advice for socioeconomically disadvantaged older people recruited via primary health care (the Do-Well study)

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Dedication: We dedicate this report to Emma Noble, the lead researcher on this project, who died tragically, aged 46, in the second year of the study. Emma was a registered general nurse who worked in the NHS for 14 years prior to her appointment to Newcastle University in September 2004. Emma worked as a researcher in the School of Neurology, Neurobiology and Psychiatry, and the School of Education, Communication and Language Sciences, before she was appointed as a Research Associate in the Institute of Health & Society. Emma worked on the Do-Well study from its inception and was central to establishing the trial. She was a highly valued member of the team. Her sudden and unexpected death was a shock, not only to her family, friends and colleagues, but also to study participants to whom she was a great source of support. She is greatly missed.

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Scientific summary

The Do-Well study

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Scientific summary

Background

There is no empirical evidence to support the hypothesis that increasing access to material or financial resources leads to improved health. A high proportion of older people in the UK do not claim the welfare benefits to which they are entitled. Welfare rights advice services are effective at maximising welfare benefits, but their impact on health has not been evaluated.

Objectives

- To establish the effects on health-related quality of life (HRQoL) of a domiciliary welfare rights advice service targeting independently living, socioeconomically disadvantaged older people (aged ≥ 60 years) identified via primary care, compared with usual practice.
- To establish the cost-consequences and the cost-effectiveness of the intervention.
- To establish the acceptability of the intervention to trial participants and relevant professionals.
- To identify the unanticipated consequences of the intervention.

Methods

Study design

We conducted a pragmatic, individually randomised, parallel-group, single-blinded (researchers), wait-list controlled trial of domiciliary welfare rights advice versus usual care, with embedded economic and quantitative and qualitative process evaluations. The trial took place in the North East of England. Data were collected by interviewers in participants' homes at baseline and 24 months, and by postal self-completion questionnaire at 12 months.

Participants, recruitment and randomisation

Working in 10 local authorities able to deliver the intervention, we identified 17 general practices that had Index of Multiple Deprivation scores for practice location within the most deprived two-fifths of the distribution for England, had no previous access to welfare rights advice services and were willing to participate. From these practices we recruited randomly selected volunteer patients aged ≥ 60 years, living in their own home, fluent in English and not terminally ill. After we gained written informed consent and collected baseline data, participants were randomised in a 1 : 1 ratio, stratified by general practice, and informed of their group allocation by letter.

Intervention and control condition

Participants allocated to the intervention group were referred for welfare rights advice, comprising face-to-face consultations and active assistance with benefit claims, delivered in participants' own homes by a qualified welfare rights advisor (WRA). We asked WRAs to deliver the initial assessment and advice sessions within 2 weeks of the baseline assessments. The participants were followed up at home or by telephone, as required, by WRAs until they no longer required assistance.

The participants in the control group received usual care until the 24-month follow-up, after which they received the intervention.

Outcome evaluation

Our primary outcome was HRQoL, measured using the CASP-19 (Control, Autonomy, Self-realisation and Pleasure) instrument at baseline and 24 months, and in addition at 12 months.

We also collected data on the following secondary outcomes: Patient Health Questionnaire (PHQ-9) depression scale; social interaction, strength of confiding relationships and social isolation; general health status [using the EuroQol-5 Dimensions-3 Levels (EQ-5D-3L)]; change in smoking, alcohol, diet and physical activity; independence and the number of hours per week of home care; mortality; Affordability Index; Standard of Living Index; and household financial status, including all income, major outgoings, debts and capital assets. At 24 months, data were collected by WRAs on new benefits received since baseline.

We assessed the potential harms of the intervention using these primary and secondary outcome measures as well as qualitative interviews.

To provide context and adjust for potential confounding, we collected data on age, sex, ethnicity, educational level attained, employment status, living arrangements, functional ability using the modified Townsend Activities of Daily Living scale, and life events.

Sample size

A minimum of 318 participants (a total of 636) needed to be followed up in each of the study arms to provide 90% power at 5% significance level to detect a 1.5-unit difference in mean CASP-19 score at 24 months. With an estimated attrition at 24 months of 15%, 750 participants needed to be recruited to the study.

Statistical analysis

We analysed outcomes on an intention-to-treat basis. Simple and multiple imputation methods were applied to deal with missing outcome data, with sensitivity analyses to explore the effect of imputation approaches. The difference between the intervention and control groups at 12 and 24 months in mean CASP-19 with 95% confidence intervals (CIs) was assessed using multiple linear regression with adjustment for baseline values and general practice.

Continuous secondary outcome variables were compared at 24 months between the intervention and control groups using multiple linear regression with adjustment for baseline values and general practice. We used logistic regression with adjustment for general practice to compare proportions between the intervention and control groups for categorical secondary outcome variables.

Bootstrap estimation was used for CIs throughout when the distribution was skewed.

Exploratory analyses were performed in which the linear model for the primary outcome contained terms for intervention, other key variables (sex, age in years and education) and the interaction between them. In addition, within the intervention group, multiple linear regression explored whether the mean CASP-19 score at 24 months differed, first between those receiving and not receiving welfare rights advice and, second, between those receiving and not receiving new welfare benefits. A comparison was also made between CASP-19 scores at 24 months for intervention arm participants who had previously been awarded a financial welfare benefit and those in the control arm who were later awarded a financial benefit. All of these models also included the participants' baseline CASP-19 score, general practice, age, gender and level of educational attainment and whether or not they were living alone.

Process evaluation

We assessed descriptively whether or not participants received the intervention as intended in terms of timeliness, reach, uptake and quality. We undertook an assessment of intervention fidelity by independent observation of one welfare rights advice session delivered by each WRA to a study participant. We also conducted semistructured qualitative interviews with 50 trial participants, purposively sampled to achieve

maximum variation with respect to group allocation, gender, age and receipt of benefits. Seventeen professional participants were interviewed, selected on the basis of their roles in service commissioning, policy, strategy and service delivery. Sampling and interviews with trial and professional participants continued until data saturation was achieved. The interviews with trial participants explored acceptability and perceived consequences of the intervention. The interviews with professional participants explored the acceptability and fidelity of the intervention and the likely implications for translation into routine practice. All interviews were digitally recorded and transcribed verbatim. A coding framework was developed and data were analysed thematically using the framework method with constant comparison and deviant case analysis to enhance validity.

Economic evaluation

The relative efficiency of the domiciliary welfare rights advice intervention was assessed in within-trial cost–consequence and cost-utility analyses to estimate the incremental cost per quality-adjusted life-year (QALY) gained. Changes in HRQoL were captured using the EQ-5D-3L questionnaire, from which scores for participant-specific health state utilities at each time point were derived. The EQ-5D-3L scores were transformed into QALYs using the 'area under the curve' method. Imprecision surrounding incremental QALYs was estimated using bootstrapping to derive 95% CIs. Sensitivity analyses were performed to assess the impact of different data sources and varying key assumptions and parameters on the cost-effectiveness of the intervention. Estimates of cost took the perspectives of public sector services (for the service delivery costs of the intervention) and the Treasury (for additional benefits awarded). Incremental cost-effectiveness ratios (ICERs) were calculated and compared with the National Institute for Health and Care Excellence's threshold of £20,000–30,000 for society's willingness to pay for one QALY gained. The probability for the intervention to be cost-effective at different willingness-to-pay thresholds was assessed using a cost-effectiveness acceptability curve.

Results

Main trial findings

Out of 3912 patients approached by general practices, 755 (19%) agreed to participate and were randomised (intervention, $n = 381$; control, $n = 374$). In the intervention group, 335 (88%) participants received the intervention. The median time to first WRA assessment and advice was 58 days (range 0–403 days) and only five (1.5%) participants were seen within 2 weeks as intended. A total of 605 (80%) participants completed the 12-month follow-up and 562 (75%) completed the 24-month follow-up. Data were available for analysis at 24 months on 283 and 279 participants in the intervention and control groups, respectively. Only 84 (22%) intervention group participants were awarded additional benefits: 65 (19.4%) financial; 14 (4.2%) non-financial and 5 (1.5%) both.

The allocation groups were balanced with regard to all outcomes and covariates. The mean age of participants was 70 years, half of participants were female and, on average, participants were less socioeconomically deprived than non-participants. Those who dropped out of the trial tended to be a little older, to be male and to have a lower average CASP-19 score at baseline.

The observed WRA consultations were delivered consistently as per protocol; all relevant applications for means-tested and non-means-tested awards and benefits were completed.

We found no evidence from our quantitative analyses of any unanticipated consequences of the intervention. In qualitative interviews, some control group participants reported receiving new welfare benefits, but we found no direct evidence that any of the control group participants independently sought welfare rights advice during the 24-month follow-up.

There was no significant difference in CASP-19 score between the intervention and control groups at 24 months (adjusted mean difference 0.3, 95% CI –0.8 to 1.5). We found a significant change in the

hours of care received per week, which increased more in the intervention group (adjusted difference 26.3 hours/week, 95% CI 0.8 to 56.1 hours/week).

In the exploratory analyses we found no significant differences in primary or secondary outcomes between those in the intervention group who received welfare rights advice versus those who did not, and those in the intervention group who received benefits versus those who did not, except that those who did not receive benefits reported significantly higher levels of physical activity at 24 months. We also found no significant differences in CASP-19 score between the 55 participants in the intervention group who were awarded financial benefits and the 48 participants in the control group (who were found to be eligible at the 24-month follow-up and were, thus, comparable on eligibility) (adjusted mean difference in CASP-19 score 1.4, 95% CI –2.0 to 4.7). We found no evidence of a dose–response relationship between amount of financial benefit received and change in CASP-19 score. We did, however, find a weak positive correlation between CASP-19 score and the amount of time since receipt of the benefit (0.39, 95% CI 0.16 to 0.58).

Qualitative study

Receipt of the intervention was acceptable, and both participants and professionals perceived the receipt of additional financial and non-financial benefits as having a positive impact on health and HRQoL. For some participants, the increased benefits allowed them to escape a stressful financial situation; alleviated some food and fuel poverty and provided security against unplanned costs; helped them to maintain their mobility and independence and to pay for formal and informal support with activities of daily living; or allowed them to provide gifts for informal help received.

Economic evaluation

The delivery of domiciliary welfare rights advice was found to be, on average, more costly and more effective than standard practice. The average total cost per participant was £44, £17 per person more than usual care. The incremental mean health gain was 0.009 (95% CI –0.038 to 0.055) QALYs, resulting in an ICER of £1914 per QALY gained. However, the probability that the intervention was cost-effective was only 60% when compared with conventional thresholds for society's willingness to pay for a QALY (£20,000) and any value above. Imprecision around all estimates was high and analyses involving multiple imputation to account for missing data yielded differing conclusions.

Discussion

Interpretation of findings and relationship to prior knowledge

This is the first randomised controlled trial to examine the impact of welfare rights advice on health outcomes and the first to explore, specifically, its impact on older people when it is delivered in their own home. The outcome analyses do not provide sufficient evidence to support domiciliary welfare rights advice as a means of promoting health among older people. These findings are somewhat surprising, given the qualitative findings, which suggest important impacts on HRQoL. Nevertheless, taking into account the potential limitations of the study, we cannot rule out the possibility that the intervention might have had a potentially beneficial effect and that this might be cost-effective.

Strengths and limitations of the methods

The trial was rigorously, ethically and legally conducted to internationally accepted standards, adhered to accepted reporting protocols and was overseen by an independent Trial Steering Committee. We employed rigorous controls to ensure data quality, and blinding to minimise bias among data collectors. Our primary and secondary outcomes were measured using validated scales, and were chosen on the basis of rigorous pilot work. The intervention and control groups were balanced on all variables, indicating appropriate and effective randomisation.

The qualitative study was rigorously conducted, with systematic and double coding of data to enhance internal validity. The participant data were corroborated using data from professional participants.

The economic evaluation was conducted from public sector and Treasury perspectives, and comprehensively explored the potential for cost-effectiveness using both cost-utility and cost–consequences analyses. The sensitivity analyses assessed the impact of different data sources and varying key assumptions and parameters on the cost-effectiveness of the intervention.

The study had a number of key limitations. The study participants were less socioeconomically deprived than expected, meaning that fewer than one-quarter were eligible for new welfare benefits. The reports of benefits received differed substantially between interview data and the data collected by WRAs at 24 months. The rate of attrition was higher than had been anticipated at the outset. There was evidence that those remaining in the study at 24 months were healthier than those who dropped out for any reason, which will also have introduced bias.

Implications for health and social care

Welfare rights advice remains an important social and economic intervention. Given that many unclaimed benefits for those aged ≥ 60 years are health related, our research suggests that it will be of value to health care if professionals opportunistically identify and refer people they believe may be eligible for unclaimed benefits.

Recommendations for further research

1. Methods need to be developed to identify patients most likely to benefit from welfare rights advice, so that they can be systematically targeted in primary and secondary care for referral to welfare rights advice services.
2. Longer-term follow-up of this trial cohort should be undertaken to identify whether or not outcomes diverge among intervention and control groups over a more extended time horizon.
3. Research is needed to better understand how to target welfare rights advice to those most in need, in relation to both welfare entitlement and capacity to benefit in health terms.
4. Further evaluations of welfare rights advice should be conducted, using alternative study designs (e.g. taking advantage of natural experiments) over extended periods.
5. Research is needed to explore further the most appropriate outcome measures for evaluating the health impacts of welfare rights advice.

Trial registration

This trial is registered as ISRCTN37380518.

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