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The effect of telecare on the quality of life and psychological well-being of elderly recipients of social care over a 12-month period: the Whole Systems Demonstrator cluster randomised trial

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Abstract

Background: home-based telecare (TC) is utilised to manage risks of independent living and provide prompt emergency responses. This study examined the effect of TC on health-related quality of life (HRQoL), anxiety and depressive symptoms over 12 months in patients receiving social care.

Design: a study of participant-reported outcomes [the Whole Systems Demonstrator (WSD) Telecare Questionnaire Study; baseline n = 1,189] was nested in a pragmatic cluster-randomised trial of TC (the WSD Telecare trial), held across three English Local Authorities. General practice (GP) was the unit of randomisation and TC was compared with usual care (UC).

Methods: participant-reported outcome measures were collected at baseline, short-term (4 months) and long-term (12 months) follow-up, assessing generic HRQoL, anxiety and depressive symptoms. Primary intention-to-treat analyses tested treatment effectiveness and were conducted using multilevel models to control for GP clustering and covariates for participants who completed questionnaire measures at baseline assessment plus at least one other assessment (n = 873).

Results: analyses found significant differences between TC and UC on Short Form-12 mental component scores (P < 0.05), with parameter estimates indicating being a member of the TC trial-arm increases mental component scores (UC-adjusted mean = 40.52; TC-adjusted mean = 43.69). Additional significant analyses revealed, time effects on EQ5D (decreasing over time) and depressive symptoms (increasing over time).

Conclusions: TC potentially contributes to the amelioration in the decline in users' mental HRQoL over a 12-month period. TC may not transform the lives of its users, but it may afford small relative benefits on some psychological and HRQOL outcomes relative to users who only receive UC.

International Standard Randomised Controlled Trial Number Register: ISRCTN 43002091.

Keywords: telecare, assistive technology, cluster-randomised trial, quality of life, older people

Introduction

Projections indicate the UK population will age with those over 65 will increasing from 17 to 25% between 2010 and

2035 [1-3]. A large proportion of older people will be living alone and they are expected to consume increasing resources which will pose major challenges to the design and implementation of social and healthcare provision [2, 4]. In the UK health and social care policy favours supporting individuals with social care needs to continue living at home rather than to move into residential care thereby concurrently reducing costs and maintaining independent living [5–8].

Telecare (TC) is one approach that is considered to have the possibility of supporting people in their own home [9], and address the rising financial expenditure of caring for an ageing population within evolving, non-nuclear familial structures. Government backed programmes in the UK and Europe, such as Delivering Assisted Living Lifestyles at Scale (DALLAS) [10], highlight the rising priority TC has assumed within social care practice. Furthermore; both European and US TC markets forecast double-figure percentage growth in the coming years, amounting to a world-wide expenditure on TC estimated at \$650 billion by 2014 [11].

TC involves electronic sensors that allow the remote, automatic and passive monitoring of individuals' personal health and safety (e.g. mobility and falls) and home environment (e.g. floods and fires). Although there are a wide variety of components, modes of kit and service provision models, TC is principally utilised to manage the risks of independent living and provide prompt emergency responses [12, 13]. The external monitoring by services ensures few demands are placed on the user and thus minimises any technical difficulties in using the technology [14]. However, the process of being monitored may raise concerns with users regarding: privacy and data protection, negative consequences of false alarms, isolation from family and support systems, compromised relationships with health and social care professionals and accelerated functional deskilling due to device usage [15].

Although there is little evidence, some maintain that these devices have the potential to improve quality of life (QoL) and psychological well-being of participants; by offering reassurance that in the event of a problem help will automatically be available [16–18].

In 2009 the Department of Health (England) funded the Whole Systems Demonstrator (WSD) evaluation of integrated care, to provide better evidence on the effectiveness of TC and Telehealth [19]. The study was a large clusterrandomised controlled trial of TC. Here, we report the impact of these services on the health-related quality of life (HRQoL) and psychological outcomes of TC recipients over a 12-month period. Other evaluation strands address healthcare utilisation and cost-effectiveness of TC [20, 21].

Methods

The detailed protocol and design for the WSD evaluations has been reported elsewhere [19]. Below we describe key features of the protocol and design relevant to the nested questionnaire TC study (see Supplementary data available in *Age and Ageing* online, Box S1).

Design and randomisation

The WSD Telecare trial (n = 2,600) was a multicentre pragmatic, cluster-RCT of TC across three local authority sites in England (Cornwall, Kent and Newham, London) with a nested questionnaire study for a subsample of participants, the WSD Telecare Questionnaire Study (n = 1,189). Allocation to trial-arm was conducted using cluster randomisation, based on participants' registration with a particular general practice (GP). The GP constituted the cluster level unit of random allocation because GP are stable organisations involved in the care of all WSD participants. The WSD Telecare Questionnaire Study involved 204 GP practices recruited across the three WSD sites.

Consenting practices were allocated to the TC (n = 101) or usual care (UC) (n = 103) group using a centrally administered minimisation algorithm devised to ensure groups of practices and were similar in terms of size, deprivation index, proportion of White patients and the presence of social care needs [19].

Neither participants nor assessors could be blinded to trial-arm allocation, due to the nature of the intervention. Participants not allocated to receive TC were informed that they would be offered the technology at the end of the trial period, following a reassessment of need.

The study protocol was approved by the Liverpool Research Ethics Committee (Ref: 08/H1005/4).

Participants

Study recruitment

Local Authority departments identified participants from area social service databases between May 2008 and December 2009. Participants were eligible for the trial if they were aged ≥ 18 years and met one or more of the following criteria/characteristics: (i) receiving night sitting, (ii) receiving ≥ 10 h per week of home care, (iii) receiving ≥ 1 days per week of day care, (iv) mobility difficulties, (v) those who have had a fall or are considered at a high risk of falling, (vi) having cognitive impairment or (vii) a live-in or nearby carer facing difficulties carrying their current support. Participants were excluded if: (i) their place of residence lacked an appropriate power supply or telephone line, (ii) TC was already installed (other than basic devices, i.e. pendant/bracelet alarm or smoke alarm not part of a TC package) or (iii) lacked the ability to understand English or were unable to complete the questionnaire with support from a researcher.

Following identification, potentially eligible participants were sent a request to complete and return a 'data-sharing letter'. After this initial agreement participants received a visit from a member of their local WSD project team who provided a consent form and patient information sheet relating to the WSD Telecare trial. At this point all non-cognitively impaired participants were offered the opportunity to take part in the nested WSD Telecare Questionnaire Study. Willing participants were contacted by trained interviewers and a baseline interview arranged in the participant's home at which point written consent for the WSD Telecare Questionnaire Study was obtained.

Intervention

Across all sites participants received a Tunstall Lifeline Connect or Connect+ base unit and pendant/bracelet alarm alongside any number of up to 27 peripheral devices. Devices were classified into four broad categories (see Supplementary data available in *Age and Ageing* online, Table S1) [14, 22, 23].

The number and type of TC devices were allocated on the basis of a needs assessment conducted by the local project team. Data from the sensors and alarms were automatically sent to the monitoring centre via a telephone line. TC alerts were monitored in real time 24-h per day. Following any alert, monitoring centre staff attempted to make contact with the individual, via the base unit or telephone, and if further assistance was required contact was made with an identified carer or emergency services, as appropriate. The TC intervention was received in addition to UC for the intervention group.

Participants in the TC trial randomised to the control arm received usual health and social care for the 12-month duration of the trial. Some control participants received a pendant/bracelet alarm as this was current UC practice (controlled for in the analysis).

Assessments

Questionnaires administered at baseline were self-completed by the participant with a trained interviewer researcher on hand to clarify the meaning of particular words or questions. The short-term (ST) assessment was conducted at 4 months (median duration = 135 days; IQR = 110–62) and a longterm (LT) assessment at 12 months (median duration = 375 days; IQR = 341–390). At ST and LT the questionnaires were posted for self-completion. At the LT follow-up nonresponders to the postal assessment were contacted by trained interviewers to arrange home visits to facilitate questionnaire completion, if required.

Measures

This paper presents the findings for HRQoL as assessed by the Short Form 12-item Survey (SF-12) [24]; the EQ-5D York-Tariff [25] summary index; the ICECAP-O [26] index of capability for older people; anxiety as assessed by the Brief STAI [27], and depressive symptoms assessed by the CESD-10 [28]. Further details of the measures can be found in Supplementary data are available in *Age and Ageing* online, Box S2, all these measures have been found to be valid and reliable in ageing populations [19, 29].

Demographic information recorded included age, gender, ethnicity, number of co-morbid conditions and level of education. Participants' levels of deprivation were allocated using an Index of Multiple Deprivation score (IMD) [30] as assessed through postcodes.

Sample size

For the WSD Telecare Questionnaire Study, a power calculation was conducted on the basis of detecting a small effect size, equivalent to a Cohen's d of 0.3, allowing for an

Statistical methods

Missing data rates (at the scale/item level used in analyses) among those returning questionnaires at ST and LT were low (\leq 7%) and were imputed (m = 10) using the SPSS MCMC function within each administration. Standard multiple-imputation procedures were employed [31]. Details of multiple-imputation processes are available from the authors.

Sample characteristics

Frequencies and mean scores are reported for each trial-arm at each follow-up. Analyses were conducted on a modified intention to treat basis, i.e. available case analyses—where data were available for baseline plus at least one follow-up point [29].

Detecting TC effects

Repeated measures in each outcome over the 1-year followup period were analysed with linear mixed-effects model (LMM) procedures to detect: trial-arm effects, time effects and their interaction. This method took account of the hierarchy within the data observations (i.e. assessment points were nested within participants, nested within GP practices). Data are presented as estimated marginal means (EMMs) with standard errors (SE).

Covariates to adjust for case-mix differences between trial-arms were age-band (see Table 1), gender, deprivation, ethnicity, co-morbidities, highest education level, WSD site, number of devices per category of kit received, dependency based on the EQ5-D self-care domain score at baseline, previous receipt of TC within social care package outside of this trial, number of adults in household and baseline outcome score. For all parameter tests the alpha level was set to 0.05; Sidak's adjustment was used to compensate for *post hoc* multiple comparisons; 95% confidence intervals (CI) were used to take into account the uncertainty in the estimates. Effect sizes for the trial arm effects of each outcome were reported as Hedge's g. Analyses were conducted in SPSS v19 [32].

Results

Sample recruitment and attrition

Of the 2,600 participants in the WSD Telecare trial, 1,189 participated in the questionnaire study, with 639 (53.7%) in the UC group and 550 (46.3%) in the TC group. ST follow-up received 535 responses (45.0%), and LT 763 (64.2%). Of

	Intervention	Control	Total	
	n = 550 (46.3%)	n = 639 (53.7%)	n = 1189	
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Site				
Cornwall	127 (23.1)	138 (21.6)	265 (22.3)	
Kent	273 (49.6)	309 (48.4)	582 (48.9)	
Newham	150 (27.3)	192 (30.0)	342 (28.8)	
Gender				
Female	345 (62.7)	420 (65.7)	765 (64.3)	
Male	205 (37.3)	219 (34.3)	424 (35.7)	
Age bands				
Young (<64 yoa)	130 (23.6)	139 (21.8)	269 (22.6)	
Young-old (65–74 yoa)	116 (21.1)	140 (21.9)	256 (21.5)	
Old-old (75-84 yoa)	169 (30.7)	209 (32.7)	378 (31.8)	
Oldest-old (>85 yoa)	135 (24.5)	151 (23.6)	286 (24.1)	
Ethnicity ^a				
Non-White	66 (12.0)	71 (11.1)	136.4 (11.5)	
White British/Irish	484 (88.0)	568 (88.9)	1052.6 (88.5)	
Previous TC				
Yes (1)	282 (51.3)	320 (50.1)	602 (50.6)	
No (0)	268 (48.7)	319 (49.9)	587 (49.4)	
Living alone ^a		. ,	. ,	
Yes (1)	285.8 (52.0)	343.2 (53.7)	629 (52.9)	
No (0)	264.2 (48.0)	295.8 (46.3)	560 (47.1)	
	Mean (SE)	Mean (SE)	Mean (SE)	
Age (years)	73.92 (0.611)	74.31 (0.539)	74.13 (0.404)	
Deprivation score ^a	27.67 (0.612)	28.56 (0.618)	28.15 (0.437)	
Number of comorbidities	1.07 (0.063)	1.11 (0.057)	1.09 (0.042)	
Amount of telecare kit	3.89 (0.072)	0.15 (0.034)	1.88 (0.066)	
Level of education ^a	0.75 (0.053)	0.60 (0.041)	0.67 (0.033)	

^aMultiply imputed; yoa, years of age.

these, 873 (73.4%) completed baseline and at least one of the follow-up assessments (443 UC; 430 TC)—the available cases cohort whose analyses are reported in this paper (see also consort diagram—Supplementary data are available in *Age and Ageing* online, Figure S1). At LT follow-up 186 (of 443, 42.0%) of the UC group completed questionnaires by post; a similar percentage of the TC arm participants completed questionnaires by post (185/430, 43.0%), indicating no apparent bias in completions by this method.

The main reasons for formal withdrawal from the questionnaire study were, service user passed away (40% of reasons provided), moving to residential or nursing care (13.7%), no longer wishing to be in the control group (12.1%), no longer wishing to be in the intervention group (6.8%) and deterioration in condition (physical or mental capacity; 11.6%). Supplementary data are available in *Age and Ageing* online Tables S2 and S3 show the characteristics of participants who withdrew and those that did not on demographic and outcome measures at baseline.

Sample characteristics

Baseline sample characteristics by trial-arm of the 1189 questionnaire participants are reported in Table 1. The mean age of the sample was approximately 74 years with the majority of participants being of white British/Irish ethnicity. The sample had on average one comorbid condition and the majority (64.8%) had received little formal education. On average the intervention group received just short of 4 pieces of TC kit (excluding the base-box and personal pendant alarm).

Detecting TC effects

Unadjusted means by trial-arm and time point on the six outcome measures for the available case cohort are available in Supplementary data are available in *Age and Ageing* online, Figure S2.

Adjusted means (EMMs) for each outcome measure by trial arm and time point are presented in Figure 1. Table 2 presents key parameter estimates for the effect of trial-arm, time and their interaction from LMM analyses (adjusting for case-mix) conducted for each outcome (parameters for covariates are not presented). The parameter estimate indicates the magnitude of score changes when moving from one group/level to another after controlling for additional variables. The SE of the parameter, an indication of its variance within the sample, is utilised to determine whether the effect is *statistically* significant.

Effect sizes for the main effects of trial arm are available in Supplementary data are available in *Age and Ageing* online, Figure S3. These revealed a significant trial-arm effect on SF12-MCS and time effects on EQ5D and depression scales. Parameter estimates indicate that being a member of the TC trial-arm increases the SF12 mental component score by ~3-points (after the intra-cluster correlation, all covariates and data hierarchy are taken into account), as indicated by the adjusted means of the MCS scale of the UC (mean = 40.52, SE = 0.88) and TC groups (mean = 43.69, SE = 0.83; P = 0.017). However, effect-size estimates reveal this to be a small effect, with large 95% CIs.

The EQ-5D score indicate that health status is reduced overall from ST (mean = 0.332, se = 0.018) to LT (mean = 0.283, SE = 0.017; P = 0.002); and the CESD-10 scale that depressed mood increased from ST (mean = 1.226, SE = 0.035) to LT (mean = 1.287, SE = 0.033; P = 0.032). Of note is the lower levels of depressed mood in the TC group (mean = 1.187, SE = 0.044) compared with the UC group (mean = 1.326, SE = 0.046) which was close to significance (P = 0.050).

Sensitivity analyses (per-protocol, complete cases and excluding covariates) indicated similar trends in effects.

Discussion

This study examined the effect of TC on participant reported outcomes in a group of individuals in receipt of social care. The results suggest that TC may limit or ameliorate declines in mental health QoL (MCS SF-12) and potentially depressive symptoms (CESD-10). These occurred in the absence of any changes in Physical QoL (SF12-PCS). TC devices may improve psychological well-being by increasing perceptions of safety and security which in turn could have improved the Mental QoL of participants [13] (sensitivity analyses

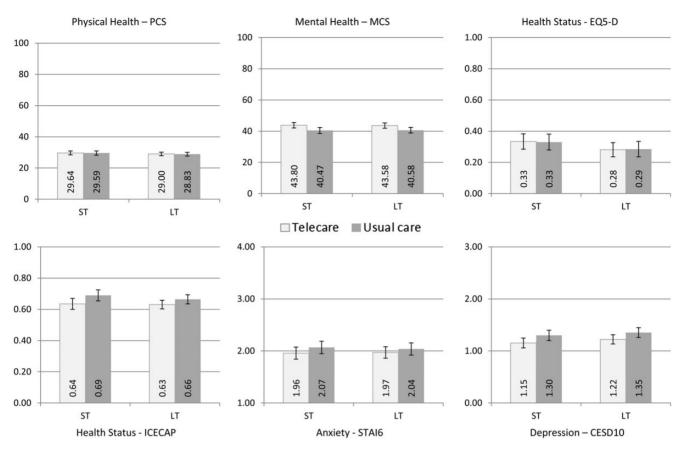


Figure 1. Adjusted (estimated marginal) means and 95% CI for the outcome variables at ST and LT follow-up trial arm.

	Trial arm			Time			Time*Trial arm		
	Est.	SE	Sig.	Est.	SE	Sig.	Est.	SE	Sig.
SF 12–PCS	-0.167	0.849	0.844	0.641	0.453	0.157	0.119	0.640	0.852
SF 12-MCS	-3.006	1.257	0.017	0.217	0.614	0.723	-0.328	0.868	0.705
EQ5D	0.004	0.034	0.896	0.053	0.017	0.002	-0.008	0.024	0.733
ICECAP	0.034	0.019	0.074	0.005	0.019	0.788	0.019	0.027	0.476
Anxiety	0.067	0.082	0.416	-0.013	0.043	0.770	0.042	0.061	0.492
Depression	0.130	0.066	0.050	-0.070	0.033	0.032	0.018	0.046	0.694

Table 2. Parameter estimates for trial arm and time in the linear mixed-effects model analyses for available cases (n = 873)

Parameter estimates for trial arm indicate the change in scores (after controlling for all other variables in the equation) between the intervention group (reference category) and the control group. For example, control group scores on the SF12-MCS are 3 point lower than intervention group. For time, the LT administration point is the reference category; so for the CESD, the ST scores were on average 0.07 lower than the long-term scores. Significant effects (P < 0.05) are indicated in bold.

confirmed this finding). The results of a small beneficial effect on mental QoL from TC are in line with previous findings [16, 17]. However, although statistically significant, there is concern the clinical significance of the effect is small, with wide confidence-intervals. That the effects on mental well-being occurred in the context of the general decline in well-being suggests that TC may be influential in avoiding reductions in the rate of decline in mental HRQoL and depressive symptoms.

No effect was found on anxiety although reduction in anxiety is one of the potential reasons for introducing TC to provide reassurance. It is possible that the impact of TC on anxiety included a complex range of positive and negative effects that resulted in very little net change in anxiety levels as measured by the Brief STAI. One may conjecture that the introduction of TC may have provided reassurance of a rapid response when needed but this may have been counterbalanced by a concomitant increase in anxiety by increasing the salience of participants' frailty. In addition, the introduction of TC may have also led to the perception that existing caring relationships and service arrangements may be reduced [33].

Strengths and limitations

The WSD Telecare trial is one of the largest (cluster) randomised trials to evaluate TC, and examine its effects over a period of 12 months in a group of individuals receiving social care. The nested WSD Telecare Questionnaire Study is one of the largest studies to evaluate TC using participantreported outcome measures. It addresses a gap in the evidence base, where there was a lack of quality studies with large sample size, randomly allocated control group, ST and LT follow-ups and use of validated questionnaires [18]. The pragmatic nature of the trial, inclusion of participants from a range of social care need categories, imposition of minimal exclusion criteria and evaluation across a number of different delivery models improve the generalisability of these findings. The use of multiple outcome measures and robust statistical methods also affords greater confidence in the reliability of the findings. Additional papers addressing the costeffectiveness of introducing TC services and the impact it has on health and social care utilisation are available [20, 21].

A potential limitation is that rates of loss to follow-up at ST (TC = 281-51.1% non-response; UC = 373-58.4%) and LT (TC = 171-31.1%; UC = 255-39.3%) were substantial and were slightly different for the intervention and control groups. This was particularly the case for older individuals and those with higher deprivation scores in the control group, (see Supplementary data available in *Age and Ageing* online, Table S2), which require further investigation. However, on outcome measures (see Supplementary data available in *Age and Ageing* online, Table S3), control and intervention group participants who withdrew had similar mean scores to those who did not, indicating withdrawal is unlikely to have a systematic impact on outcomes.

It is probable, attrition rate of loss to follow-up was slightly higher at ST follow-up as questionnaires were administered almost exclusively as a postal survey, whereas researchers to assist the participant were available at baseline and if required at LT follow-up. The control and intervention groups' rates differed only slightly, however, potentially limiting bias towards the intervention group; furthermore the groups were evenly balanced in terms of most observed baseline characteristics (see Table 1).

A further limitation was the inability (logistically) to blind researchers and service-providers to the group allocation of the participant, and the risk of bias that this introduces into the trials (e.g. service-providers inadvertently favouring the TC group).

Although the 12-month period employed was a long follow-up in compared with existing research, there remains a need to monitor for longer periods to ascertain whether the benefits indicated here are maintained [18].

The present analysis sought to draw conclusions about a general class of assistive technology, TC, in accordance with the trial protocol, which was designed to replicate likely regional differences in a potential rollout of TC services and in this way to facilitate the generalisability of the finding. The effects of specific monitoring devices (e.g. fall detector and heat sensors) were not investigated, but devices were categorised and this was controlled for in the analyses.

Unfortunately, it was not possible to investigate the rates of sensor activations or false alarms (which may, for example,

The WSD telecare questionnaire study

have detrimental effects on confidence in the system for users, carers and service-providers, and/or cost implications), as these data were not available from manufacturers. However, it is recognised that the balance between userindependence, social well-being, privacy and protection, service user and health/social care professionals' confidence in systems, poor implementation and substantial integration of TC services are critical for their successful implementation.

Conclusion

This study suggests that TC has the potential to make small contributions to the amelioration in the decline in users' mental HRQoL and depressive symptoms over a 12-month period. However, the high expectations as to what TC can realistically provide for older and social care populations should be tempered by caution. The evidence presented suggests that TC may not transform the lives of its users, but it has the potential to afford small relative benefits on some psychological and HRQOL outcomes.

Key points

- This paper reports from one of the largest investigations on the effects of tele-assistive devices, the WSD study.
- It suggests that TC, relative to UC, may limit or ameliorate declines in mental health as measured by the SF12.
- Psychological effects of TC interventions, should be taken into account, when introducing TC services.

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Authors' contributions

S.H., M.B. (Beynon) (SH & MB joint first authors), M.C. and L.R. conducted preliminary analyses under the supervision of H.D. S.H. and M.B. conducted the final analyses and drafted the manuscript with S.N., H.D., P.B., M.B. (Bardsley), M.K., C.H., A.R., C.S., R.F., J.H., S.H. and S.N. contributed to development of the overall WSD study protocol. S.N. is the Principal Investigator for the WSD Evaluation. H.D. is the trial statistician and guarantor of statistical quality for the WSD Evaluation; S.H., M.B. (Beynon), and L.R. and S.N. contributed to the planning of the questionnaire data collection; M.C., S.H., L.R. and M.B. (Beynon) co-ordinated the daily implementation of the questionnaire assessment protocol and maintained trial data. H.D., S.H., M.C., M.B.

S. P. Hirani et al.

(Beynon), L.R., A.S. and C.H. contributed to planning of the analyses. All the authors reviewed and approved the manuscript. The Evaluation Team met regularly during the trial period, reviewed interim documents and preliminary analyses, and contributed as a whole to discussions of the analytic strategy.

Conflicts of interest

All authors conform to a competing interest statement and declare: support from the Department of Health and the University College London Hospitals and University College London; several authors have undertaken evaluative work funded by government or public agencies but these have not created competing interests; no other relationships or activities that could appear to have influenced the submitted work.

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Ethical approval

The study was approved by Liverpool Research Ethics Committee (ref: 08/H1005/4).

Supplementary data

Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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The impact of first- and second-eye cataract surgery on injurious falls

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The impact of first- and second-eye cataract surgery on injurious falls that require hospitalisation: a whole-population study

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Abstract

Background: cataract is a leading cause of reversible vision impairment and may increase falls in older adults.

Objective: to assess the risk of an injury due to a fall among adults aged 60+, 2 years before first-eye cataract surgery, between first-eye surgery and second-eye surgery and 2 years after second-eye surgery.

Design: a retrospective cohort study.

Setting: Western Australian Hospital Morbidity Data System and the Western Australian Death Registry.

Subjects: there were 28,396 individuals aged 60+ years who underwent bilateral cataract surgery in Western Australia between 2001 and 2008.

Methods: Poisson regression analysis based on generalised estimating equations compared the frequency of falls 2 years before first-eye cataract surgery, between first- and second-eye surgery and 2 years after second-eye cataract surgery after accounting for potential confounders.

Results: the risk of an injurious fall that required hospitalisation doubled (risk ratio: 2.14, 95% confidence interval: 1.82 to 2.51) between first- and second-eye cataract surgery compared with the 2 years before first-eye surgery. There was a 34% increase in the number of injurious falls that required hospitalisation in the 2 years after second-eye cataract surgery compared with the 2 years before first-eye surgery (risk ratio: 1.34, 95% confidence interval: 1.16–1.55).

Conclusions: there was an increased risk of injurious falls after first- and second-eye cataract surgery which has implications for the timely provision of second-eye surgery as well as appropriate refractive management between surgeries.

Keywords: cataract, falls, injury, cataract surgery, older people