

Effectiveness of educational interventions for informal caregivers of individuals with dementia residing in the community: systematic review and meta-analysis of randomised controlled trials

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Objective: This study aims to assess whether educational programmes for caregivers of individuals with dementia living in the community are effective on caregiver burden, quality of life (QoL), depression and transitions to long stay care compared with usual care.

Method: MEDLINE, EMBASE, PsycINFO, CINAHL, AgeLine, CENTRAL and ERIC were searched with no restrictions on language or publication status in February 2013. Randomised controlled trials (RCTs) were eligible. Participants were informal caregivers undertaking day to day care of an individual with dementia living in the community. Interventions were educational programmes aimed at teaching skills relevant to dementia caring. Two authors independently assessed studies for eligibility, assessed risk of bias and extracted data.

Results: We screened 1390 citations and included seven RCTs with 764 participants. Meta-analysis of five trials showed a moderate effect on carer burden (Standardised Mean Difference (SMD) = -0.52; 95% confidence interval (CI) -0.79 to -0.26; $I^2 = 40\%$). Meta-analysis of two trials showed a small effect on depression (SMD = -0.37; 95% CI -0.65 to -0.09; $I^2 = 0\%$). There was no effect on number of transitions to long stay care (relative risk 1.29; 95% CI 0.80 to 2.08). Effect on QoL was not estimable as studies varied in reporting of sub-domains and constructs within scales.

Conclusion: Educational programmes have a moderate effect on caregiver burden and a small effect on depression. Evidence of an effect on QoL and transitions to long stay care remains unclear. Copyright © 2014 John Wiley & Sons, Ltd.

Key words: caregiver education; dementia; carer burden; systematic review

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Introduction

Dementia is one of the leading causes of disability in later life. Worldwide, the number of people living with dementia is expected to rise to over 100 million in year 2050 (WHO, 2012). A large proportion of care to this patient group is delivered in the community by informal carers (Hollander *et al.*, 2009). Caring for older people with dementia puts a large burden on informal caregivers and reduces their physical and psychological

well-being (Schulz and Beach, 1999; Pinquart and Sörensen, 2006). The psychological strain associated with caring is a global issue evident in both low/middle income countries and high income countries (Schneider *et al.*, 1999; Prince, 2004). Effective interventions that can reduce the stress of caring for a dementia patient are therefore urgently required.

Previous systematic reviews have examined the effects of various information interventions for caregivers and have reported small or inconclusive effects

across the domains of carer burden, mental health and quality of life (QoL) (Thompson *et al.*, 2007; Parker *et al.*, 2008; Corbett *et al.*, 2012). This review will extend the work of earlier systematic reviews and will have a narrower scope by focussing solely on educational programmes for caregivers.

The primary objective of this systematic review of randomised controlled trials (RCTs) was to evaluate the effectiveness of educational interventions compared with usual care on carer burden and QoL in informal caregivers of individuals with dementia residing in the community. The secondary objective was to evaluate the effectiveness of the intervention on caregiver depression and number of transitions to long stay care.

Methods

Eligibility criteria

Eligible studies were RCTs from any geographic or socioeconomic setting. Participants included informal caregivers of individuals with dementia residing in the community. Informal caregivers were defined as unpaid, non-professionals who take extraordinary day to day care of an individual with dementia. Interventions were defined as educational interventions aimed at teaching skills relevant to dementia caring, for example, communication skills, coping and management strategies, facts about dementia and availability of support services. Educational material or informal education provided as part of routine clinical consultations with health professionals were not deemed an intervention. Specialised interventions that focus on one or two domains only, for example, communication skills or anger management, or interventions with a strong cognitive behavioural approach were not included. Multi-component interventions with education in combination with other interventions were not eligible, for example, support groups, case management and individual counselling sessions.

Comparators were usual care, which may include pharmacological intervention and provision of access to some information sources and support services, e.g. support groups. The primary outcomes were carer burden and caregiver's QoL. Secondary outcomes included caregiver depression and number of transitions to long stay care.

Information sources and search

We searched MEDLINE, PsycINFO, EMBASE, CINAHL, AgeLine, ERIC and CENTRAL via The Cochrane

Library. The last search was run on 5 February 2013. Unpublished studies were sought from OpenGrey and Proquest. Web of Science were searched for conference proceedings from February 2010 to February 2013.

We used the following search terms to search all trial registers and databases: *dement**, *alzheimer**, *caregiver**, *carer**, *learn**, *education**, *information**, *support**, *psychoeducation**, and *train**. The Cochrane highly sensitive search strategy for identifying randomised trials (Higgins and Green, 2011) was applied to MEDLINE. The filter described by Lefebvre *et al.* (2008) was applied to EMBASE and adopted for all other databases searched. There were no restrictions on language or year of publication. The full search strategies are listed in Appendix 1.

Study selection

Two authors (I. A. and M. J.) independently screened the titles and abstracts of the citations identified by the search to determine which papers met the eligibility criteria. We searched for the full text article for all citations that either author had identified as relevant or possibly relevant. The two authors then independently reviewed each full text article for inclusion. Disagreements were resolved by consensus with a third reviewer (G. M.). For full text screening, we applied Cohen's weighted kappa to assess agreement.

Data collection process

One review author extracted the data using a data extraction form, and the second author (G. M.) verified the data. Disagreements were resolved by discussion. Data were abstracted from the forms and entered into Review Manager (version 5.1) for analysis.

Risk of bias in individual studies

We assessed the risk of bias for each study in an unblinded manner using the Cochrane Risk of Bias tool (Higgins and Green, 2011). Risk of bias was assessed per study and summarised in a Risk of Bias Table. We assigned a summary assessment for each important outcome 'low risk of bias', 'unclear risk of bias' and 'high risk of bias' as per Cochrane Handbook (Higgins and Green, 2011).

Statistical analysis

For continuous variables (carer burden, QoL and depression), the summary measure was the mean difference or standardised mean difference (SMD) between groups at study end point. We used summary measures adjusted for baseline imbalances when reported. The effect of the intervention on transition to long stay care was measured using relative risk (RR) of admission to a long stay facility. We combined data when validated scales were used, when scales measured similar constructs and when it was clinically meaningful to combine outcome data at follow-up time points across studies.

We pooled effect sizes for each outcome across studies. The meta-analyses were performed by the random effects model using RevMan. For continuous outcome variables, we used the generic inverse variance method where some or all trials reported the outcome as the difference in means or the SMD. SMD and 95% confidence intervals and two-sided *p*-values for each effect were calculated.

We performed sensitivity analyses excluding studies with high risk of bias and considered pooled estimates of effect from trials with low and moderate risk of bias the definitive effect estimates of this systematic review.

Point estimates of all pooled effects and 95% confidence intervals were converted back to relevant scores on a representative scale for the purposes of assessing clinical effect. We used pooled standard deviation (SD) of baseline outcome measures of a representative study for conversion from SMD to a validated scale. In order to validate this conversion, we compared this pooled SD with SDs reported in observational studies of similar populations where possible.

We tested for heterogeneity using the chi-squared test (Cochran *Q* test) and applied a *p*-value of 0.10 to determine statistical significance as the included studies were few and small in sample size. The *I*² statistic was used to measure inconsistency across studies.

We hypothesised *a priori* that the effect size may differ according to risk of bias of the studies, duration of the educational programme (<10 h vs >10 h) and format of the intervention (group vs one to one) and set out to explore if any of the above could explain any heterogeneity observed in this systematic review.

We evaluated publication bias by means of a funnel plot for each primary outcome. The symmetry of the plots was assessed visually only as available statistical tests for publication bias are underpowered for the small number of trials included in this review. Selective outcome bias across studies was assessed by way of cross-checking reported outcomes with those listed in the methods section of each study.

We summarised the findings in a summary of findings table in accordance with GRADE methodology (Guyatt *et al.*, 2011; Higgins and Green, 2011).

Results

Study selection

The search of databases yielded 2533 citations, and one additional study was identified from the bibliographies of included studies and relevant systematic reviews. We removed 1144 duplicates. We independently screened the title and abstracts of the remaining 1390 articles. This process resulted in the exclusion of 1322 articles. The remaining 68 full text articles were screened independently by the two authors M.J. and I.A. There was excellent agreement on eligibility (Cohen's weighted kappa = 0.83). A flow diagram of the study selection process is presented in Figure 1.

Study characteristics

In Table 1, we present the characteristics of the seven included RCTs (Hepburn *et al.*, 2001; Gavrilova *et al.*, 2009; Martin-Carrasco *et al.*, 2009; Kurz *et al.*, 2010; Pahlavanzadeh *et al.*, 2010; de Rotrou *et al.*, 2011; Guerra *et al.*, 2011). All trials were parallel trials, four were single-centre trials and three were multi-centre trials. Sample sizes ranged between 50 and 292. In the five trials that categorised dementia severity, the patients cared for had mild/moderate dementia measured by standardised criteria. All trials examined the effects of a structured education programme devised to cover a set of pre-defined topics relevant to dementia caring and the caregiver role. Three trials were one-to-one based education, and four evaluated group-based education programmes. The total duration of education ranged from 2.5 to 24 h with an average duration of about 10 h. In all studies, the interventions were delivered by health professionals. All control interventions were usual care and/or waiting list control. Usual care varied between settings. In two studies (Martin-Carrasco *et al.*, 2009; Kurz *et al.*, 2010), there was some level of education and provision of information on formal services and support; in five studies (Hepburn *et al.*, 2001; Gavrilova *et al.*, 2009; Pahlavanzadeh *et al.*, 2010; de Rotrou *et al.*, 2011; Guerra *et al.*, 2011), the comparator was usual care with no further clarifiers. The primary outcomes, QoL and carer burden, were reported in four studies (Gavrilova *et al.*, 2009; Martin-Carrasco *et al.*, 2009; Kurz *et al.*, 2010; Guerra *et al.*, 2011) and six studies (Hepburn *et al.*, 2001;

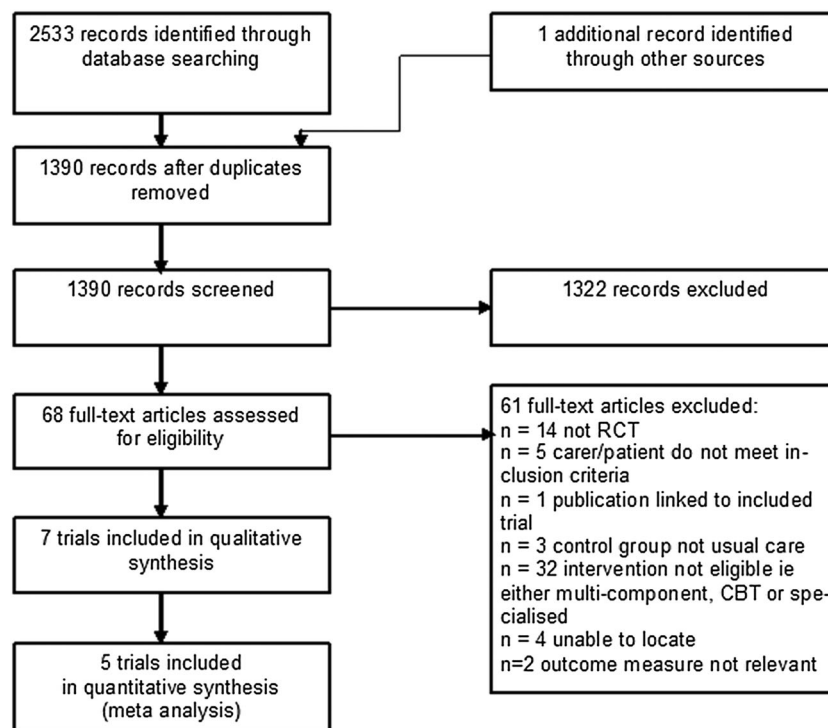


Figure 1 Systematic review flowchart: selection of trials.

Gavrilova *et al.*, 2009; Martin-Carrasco *et al.*, 2009; Pahlavanzadeh *et al.*, 2010; de Rotrou *et al.*, 2011; Guerra *et al.*, 2011), respectively. Caregiver depression was reported in three studies (Hepburn *et al.*, 2001; Kurz *et al.*, 2010; de Rotrou *et al.*, 2011) and number of transitions to long stay care in one study (Kurz *et al.*, 2010). Follow-up times ranged from 2.5 to 15 months.

Risk of bias

In Figure 2, we present the authors' risk of bias assessment of the seven included trials. Of these, six reported random sequence generation and four concealed allocation. Two reported blinding of health care providers not involved in the study and four blinded outcome assessors. Because of the nature of the intervention, study participants and deliverers of the education programme could not be blinded.

Three studies had follow-up of greater than 85% or imputation of incomplete outcome data. All of these reported comprehensively on reasons for attrition. Four studies were deemed to be at unclear risk of bias due to incomplete outcome data. There was no evidence of selective outcome reporting in the trials. Three studies

reported adherence to intention to treat analysis, and in the remainder, this was not mentioned.

Overall, four studies (Gavrilova *et al.*, 2009; Kurz *et al.*, 2010; de Rotrou *et al.*, 2011; Guerra *et al.*, 2011) were deemed by the authors to be at low risk of bias, two studies (Hepburn *et al.*, 2001; Martin-Carrasco *et al.*, 2009) at unclear risk of bias and one study (Pahlavanzadeh *et al.*, 2010) was classified as being at high risk of bias.

Results of individual studies and synthesis of data

Carer burden. Six trials, involving 445 caregivers, reported on carer burden; all applied the Zarit Burden Scale (Hepburn *et al.*, 2001; Gavrilova *et al.*, 2009; Martin-Carrasco *et al.*, 2009; Pahlavanzadeh *et al.*, 2010; de Rotrou *et al.*, 2011; Guerra *et al.*, 2011). Higher scores on this scale indicate a great degree of carer burden. The pooled analysis of the five trials ($n = 395$) with low to moderate risk of bias showed a moderate effect of education on carer burden ($SMD = -0.52$; 95% confidence interval (CI) -0.79 to -0.26 ; $I^2 = 40\%$; Figure 3). We used the pooled SD (15.6) of carer burden at baseline in de Rotrou *et al.* (2011) to translate the effect to the Zarit Burden

Table 1 Characteristics of included studies

Source	Funding	Participants	Intervention and comparator	Outcomes
de Rotrou <i>et al.</i> , 2011	Governmental	France N = 115	Multicentre: 15 sites Content: Facts dementia, communication skills, coping strategies, knowledge of formal services, behaviour management, crisis management. Group based 24 h over 12 weeks Comparator: Waiting list/usual care	Carer burden, Depression Follow-up: 3 and 6 months
Gavrilova <i>et al.</i> , 2009	WHO	Russia N = 53	Single Centre Contents: Facts about dementia Communication skills, Coping strategies, Informal social support, Knowledge about formal services, Behaviour management, Anger management, Planning for the future. 2.5 h over 5 weeks One to one. Comparator: Waiting list control, usual care with no further clarifiers	Carer burden, QoL Follow-up: 6 months
Guerra <i>et al.</i> , 2011	Not-for-profit	Peru N = 56	Single centre Contents: Facts about dementia Communication skills, Coping strategies, Informal social support, Knowledge about formal services, Behaviour management, Anger management, Planning for the future 2.5 h over 5 weeks. One to one Comparator: Waiting list control, usual care with no further clarifiers	Carer burden, QoL Follow-up: 6 months
Hepburn <i>et al.</i> , 2001	Governmental	USA N = 94	Single centre Contents: Facts about dementia, coping strategies, behaviour management, caregiver role, psychological support/CBT at limited level 14 h over 7 weeks Group-based teaching Comparator: Waiting list control	Carer burden, depression Follow-up: 5 months
Kurz <i>et al.</i> , 2010	Governmental	Germany/Austria/Switzerland N = 292	Multi-centre: 15 sites Contents: Facts about dementia, coping strategies, knowledge about formal services, behaviour management, caregiver role, planning for the future, anger management 10.5 h +	QoL, depression, admissions to long stay facility Follow-up: 15 months

Table 1. (Continued)

Source	Funding	Participants	Intervention and comparator	Outcomes
Martin-Carrasco <i>et al.</i> , 2009	Private for profit	Informal carers, mean age IG/CG 63/62 years. Patients moderate dementia on average, >65 years	follow-up over 14 weeks + follow-up to 15 months Group-based teaching. Comparator: Usual care with some support and/or education	Carer burden, QoL Follow-up: 4 and 10 months
		Spain N = 104	Multicentre: 11 sites Contents: Facts about dementia, coping strategies, behaviour management and some psychological support/CBT. 12 h over 4.5 months One to one	
Pahlavanzadeh <i>et al.</i> , 2010	Educational sector	Informal carers, mean age IG/CG 55/62 years, no psychosocial intervention in last year, co-habitant with patient, Zarit score >22 Patient: Dementia mild/moderate	Comparator: Usual care with some level of support and education/information	Carer burden Follow-up: 2.5 months
		Iran N = 50	Single centre Contents: Facts about dementia, communication strategies, behaviour management, caregiver role, anger management 7.5 h over five weeks Group-based teaching	
		Informal carers, mean age IG/CG: 43/47 years, no participation in education in past, main carer Patient: Dementia moderate on average	Comparator: Usual care	

IG/CG, intervention group/control group; QoL, quality of life; WHO, World Health Organisation.

Scale. This yielded an average score of 8.1 points (95% CI 4.1 to 12.3) less for caregivers receiving the intervention compared with those receiving usual care. The SD applied is similar to that observed in an observational study (Agüera-Ortiz *et al.*, 2010) of caregivers of individuals with dementia, which reported an SD of 18.8 on the Zarit Burden Scale.

We explored possible explanations for the moderate heterogeneity observed in the meta-analysis using the subgroup analyses specified *a priori*

including format of delivery and duration of the intervention.

There was a trend towards a difference in effect on carer burden in the subgroup of trials with one-to-one delivery (SMD = -0.67; 95% CI -1.05 to -0.29; $I^2 = 39\%$) versus group-based delivery (SMD = -0.29; 95% CI -0.58 to -0.01; $I^2 = 0\%$). However, the difference between subgroups was not significant ($p = 0.12$), and the subgroup analysis did not remove heterogeneity in those who received the intervention on a one-to-one basis.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of health care providers	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
De Rotrou 2011	+	+	?	+	+	+	+
Gavrilova 2009	+	+	+	+	+	+	+
Guerra 2011	+	+	+	+	+	+	+
Hepburn 2001	+	?	+	+	?	+	?
Kurz 2010	+	+	?	+	?	+	+
Martin-Carrasco 2009	+	?	+	+	?	+	+
Pahlavanzadeh 2010	?	+	+	+	?	+	?

Figure 2 Risk of bias summary: review authors' judgement about each risk of bias item for each included study.

We found a difference in effect on carer burden in programmes of short duration (SMD = -0.86 ; 95% CI -1.24 to -0.47 ; $I^2 = 0\%$) versus those of longer duration (SMD = -0.36 ; 95% CI -0.60 to -0.13 ; $I^2 = 0\%$). The difference between subgroups was statistically significant ($p = 0.03$), and the subgroup analysis removed all heterogeneity within groups. We considered other explanations *post hoc* and found that this same analysis also separates trials into settings in low versus high income countries with greater effect seen in low income countries.

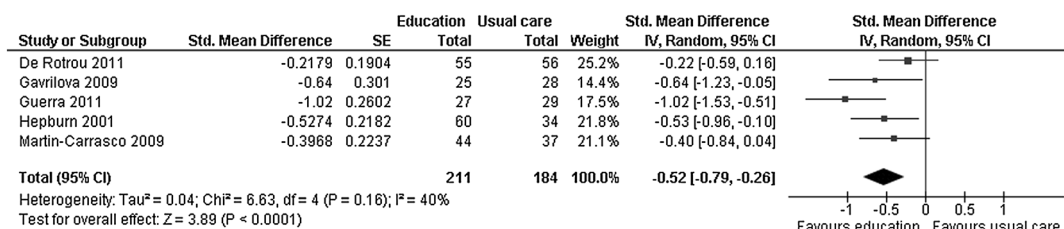


Figure 3 Carer burden in caregivers of individuals with dementia receiving education versus usual care; studies with moderate or low risk of bias. Mean follow-up 6.6 months.

Quality of life. Four studies (Gavrilova *et al.*, 2009; Martin-Carrasco *et al.*, 2009; Kurz *et al.*, 2010; Guerra *et al.*, 2011) reported on QoL for caregivers with a mean follow-up time of 9 months. Two different scales were applied (SF-36 and WHO-QOL-BRES), and effects were reported by sub-domain only. Martin-Carrasco *et al.* (2009) reported on all eight sub-domains of the SF36, whereas Kurz *et al.* (2010) reported on three of the eight sub-domains. The WHO-QOL has four sub-domains, all of which were reported on by Guerra *et al.* (2011) and Gavrilova *et al.* (2009). None of the included studies reported an overall QoL score. Although there was some overlap of sub-domains reported, differing constructs were measured within scales across studies. We therefore deemed it inappropriate to attempt a meta-analysis. Two authors found that educational programmes had significant effect on 'emotional role' sub-domain (Martin-Carrasco *et al.*, 2009; Kurz *et al.*, 2010), and two did not measure this construct (Gavrilova *et al.*, 2009; Guerra *et al.*, 2011). One study (Martin-Carrasco *et al.*, 2009) reported significant effect on the sub-domains covering physical role and functioning, general health, vitality and bodily pain. Two studies (Gavrilova *et al.*, 2009; Guerra *et al.*, 2011) found no effect on the physical sub-domain, and one study (Kurz *et al.*, 2010) did not report on this domain. Two studies (Martin-Carrasco *et al.*, 2009; Guerra *et al.*, 2011) reported a statistically non-significant trend towards effect on social role sub-domains. There was no effect in any of the four studies on psychological and environmental sub-domains.

Depression. Three studies (Hepburn *et al.*, 2001; Kurz *et al.*, 2010; de Rotrou *et al.*, 2011) reported on depression with follow-up times of 5, 6 and 15 months, respectively. It is not clinically meaningful to pool this outcome measure because of the varied length of follow-up time in these studies. We therefore pooled results of the two studies with follow-up time points at 5 and 6 months. The analysis showed a small effect on depression of education compared with usual care (SMD = -0.37 ; 95% CI -0.65 to -0.09 ; $I^2 = 0\%$;

Figure 4). We used the pooled SD (8.4) of the Montgomery–Asberg Depression Rating Scale (MADRS) depression scale at baseline in de Rotrou *et al.* (2011) to translate the effect to the MADRS scale. This yielded an average effect of the intervention of 3.1 points lower on the MADRS scale (95% CI 0.8 to 5.6)—a small effect with a CI ranging from negligible to moderate effect. The study with follow-up at 15 months (Kurz *et al.*, 2010) found no effect on depression (SMD = 0.12, 95% CI −0.15 to 0.38, $n = 221$).

Number of transitions to long stay care. One study (Kurz *et al.*, 2010) reported on the number of transitions to long stay care (intervention group 34/156 and control group 23/136) and found no effect of the intervention at 15 months follow-up (RR 1.29; 95% CI 0.80 to 2.08).

Risk of bias across studies

Visual assessment of an inverted funnel plot for the carer burden outcome did not suggest publication bias. However, with the small number of trials reporting on this outcome and the lack of a sufficiently powerful statistical test to formally test for publication bias when few studies are included, this assessment is inconclusive.

The summary of the overall evidence is presented in a GRADE profile (Table 2).

Discussion

We found moderate effect on carer burden with moderate heterogeneity between studies in a meta-analysis of five trials of with 395 caregivers. It was not possible to estimate the overall effect of the intervention on QoL of carers as studies reported different subdomains and constructs within scales that were not appropriate to combine. Meta-analysis of two trials (215 caregivers) found a small positive effect on depression in carers receiving the intervention. One of the included studies reported the effect of the intervention on transition of patients to long stay care

and found no significant difference between intervention and control groups.

We sought to examine heterogeneity by performing subgroup analyses. The finding that short courses are more effective than longer courses was surprising and unexpected. We therefore considered other explanations for the results of this analysis *post hoc*. We found a statistically significant subgroup difference in effect in high versus low income countries with higher effect on caregiver burden seen in low income countries. We hypothesise that this difference may be due to lesser standards of usual care in the low income countries. Hence, the higher effect seen in the two low income countries (Peru and Russia) may be due to poorer provision of usual care for carers and patients in the control group in these studies. In the developing world, government health services are not as readily available, and in relative terms, families from the poorer countries spend a greater proportion of their income on healthcare for the person with dementia (Prince, 2004).

We found the quality of the evidence for education of caregivers moderate for caregiver burden and low for QoL, depression and number of transitions to long stay care.

Overall, the evidence is relatively robust to determine the comparative effectiveness of education on caregiver burden. Earlier systematic reviews have called for high quality trials to build on the heretofore weak evidence base (Thompson *et al.*, 2007; Parker *et al.*, 2008; Corbett *et al.*, 2012). This systematic review includes two additional RCTs not previously included in meta-analyses, and we conclude that educational interventions may have a role to play in reducing carer burden. Included trials were carried out in both high and low income countries, and consequently, standards of usual care varied between these two settings. The fact that an average effect is seen across these settings would suggest broad applicability of the intervention. However, dementia is a complex disorder, which progresses at different rates in different individuals. Perceived burden in caring is also complex, and the potential to benefit from educational interventions will vary at an individual level. It has been proposed that the concept of burden is difficult

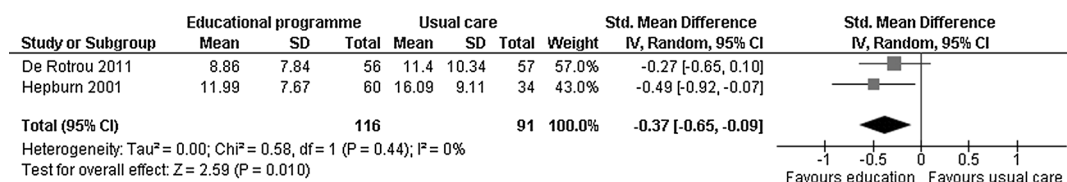


Figure 4 Depression in caregivers of individuals with dementia receiving education versus usual care.

Table 2 Summary of findings table

Educational programmes compared with usual care for informal caregivers of individuals with dementia						
Patient or population: informal caregivers of individuals with dementia Settings: the community Intervention: educational programmes Comparison: usual care						
Illustrative comparative risks ^a (95% CI)						
Outcomes	Assumed risk	Corresponding risk	Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Usual care	Education				
Carer burden: Zarit Caregiver Burden Interview (ZBI), follow-up: mean 6.6 months	The mean carer burden across control groups ranged from 27–59 on the Zarit Burden Interview Scale	The mean carer burden in the intervention groups was 0.52 standard deviations lower (0.79 to 0.26 lower), which corresponds to 8.1 points (4.1 to 12.3) lower on the ZBI scale ^b		395 (five studies)	⊕⊕⊕⊕ moderate ^c	Lower score indicates less caregiver burden. Caregiver burden was evaluated using the random-effects model
Depression: Depression scales (MADRS & CES-D), follow-up: mean 5.5 months	The mean depression in the control groups was 11 on MADRS scale ^d	The mean depression in the intervention groups was 0.37 standard deviations lower (0.65 to 0.09 lower), which corresponds to 3.1 points (0.8 to 5.6) lower on the MADRS scale ^e		215 (two studies)	⊕⊕⊕⊕ low ^{f,g}	Lower score indicates improvement. Minimal clinically important difference has been estimated at 1.6 to 1.9 on the MADRS scale
Quality of life: Quality of Life Scales (SF36, WHO-QOL-Bref), follow-up: mean 9 months	See comment	See comment	Not estimable	428 (four studies)	⊕⊕⊕⊕ low ^{h,i}	Effect not pooled as different sub-domains/constructs and scales reported
(Continues)						

Table 2. (Continued)

Educational programmes compared with usual care for informal caregivers of individuals with dementia						
Patient or population: informal caregivers of individuals with dementia Settings: the community Intervention: educational programmes Comparison: usual care						
Outcomes	Illustrative comparative risks ^a (95% CI)			Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk				
	Usual care	Education				
Number of transitions to long stay care: events, follow-up: mean 15 months	169 per 1000	218 per 1000 (135 to 352) ^j		RR 1.29 (0.8 to 2.08)	292 (one study)	⊕⊕⊕⊕ low ^{k,l}
Events are transitions to long stay care						

^aThe basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI, confidence interval; RR, risk ratio; MADRS, Montgomery–Asberg Depression Rating Scale.

GRADE Working Group grades of evidence.

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

^bSD for conversion of effect to the ZBIS based on SD = 15.6 (de Rotrou *et al.*, 2011).

^cDowngraded by one level because of two factors: (a) Moderate risk of bias: outcome assessors unblinded and allocation concealment unclear in two studies. (b) Moderate heterogeneity,

$I^2 = 40\%$ —unexplained by *a priori* subgroup hypotheses.

^dAssumed risk based on control group mean at endpoint in de Rotrou *et al.*, (2011).

^eSD for conversion of effect to the MADRS scale based on SD = 8.4 (de Rotrou *et al.*, 2011).

^fRisk of bias: Outcome assessors unblinded and allocation concealment unclear in one study.

^gWide CI: From negligible to moderate effect.

^hInconsistency not estimable as meta-analysis not undertaken.

ⁱDowngraded two levels because of very serious imprecision: Effects of subdomains varies across studies from no effect to significant effect.

^jAssumed risk based on control group risk in the included study (Kurz *et al.*, 2010).

^kOne study reporting on this outcome: inconsistency not estimable.

^lDowngraded two levels because of very serious imprecision: CI very wide ranging from negligible benefit to some harm.

to define, lacks conceptual precision (Acton and Kang, 2001) and appears insensitive to change (Cooke *et al.*, 2001). In this context, an average moderate effect on caregiver burden is clinically meaningful.

For other outcomes in this review, including depression and transition to long stay care, evidence of an effect is not as robust for a number of reasons: First, not all studies included measures of these outcomes, and the estimates of effect were imprecise. Second, the minimal clinically important difference in the MADRS depression scale in randomised studies of depression has been estimated at 1.6 to 1.9 points (Duru and Fantino, 2008). Although the average effect seen in this review is greater than the minimal clinically important difference, it should be interpreted with caution. For trials with a follow-up time of 5–6 months in this review, the effect estimate ranged from negligible effect to moderate effect. In an earlier systematic review, Thompson *et al.* (2007) found a moderate effect on psycho-educational group intervention on depression but no effect on individual psycho-educational interventions.

Lastly, a systematic review of non-pharmacological interventions to delay institutionalisation (Spijker *et al.*, 2008) found that multi-component interventions are effective. This contrasts the finding of this review that educational programmes in isolation are not effective. However, this is solely based on one study (Kurz *et al.*, 2010). The applicability of an intervention to delay admission to long stay care is not readily generalisable as it is dependent not just on interventions and clinical factors but on availability of services, cultural traditions and a host of other individual factors. The effect seen in this review on admission to long stay care should therefore be interpreted with caution.

Limitations

This review has several limitations. Some of the trials were small in sample size and underpowered, leading to imbalance in confounders in treatment groups at baseline. We mitigated against this by selecting adjusted outcome measures when they were available; however, adjusted outcomes were not available for all trials. A small number of trials were included in the pooled analysis, reducing the power of the meta-analysis. For one outcome, we estimated the effect on the basis of just one trial because of lack of measurement of this outcome in the other included trials.

We were unable to estimate the summary effect of one of the primary outcome measures, QoL. The use of dissimilar scales, with constructs only partly similar, hampered the pooling of this outcome. Our difficulty

in pooling effects across studies for this domain exemplifies the importance of selecting appropriate outcomes in clinical trials and developing core outcome sets in order to compare directly the effects of different interventions (Williamson *et al.*, 2012).

The mean follow-up time varied between 5 and 10 months in the trials we included in the final meta-analysis. We were unable to assess more long term effects of the intervention on the outcomes. For example, it would be of interest to assess whether the moderate effect in care burden is sustained over a longer time span.

Some studies were at risk of selection bias because of inadequate allocation concealment, and non-blinding of outcome assessors in two trials could have led to ascertainment bias. These biases may have led to an overestimate of effect. Social desirability bias is prominent in these trials given the subjective nature of outcomes, and this may lead to an underestimate. Several of the trials suffer from incomplete outcome data, suggesting attrition bias, and we did not attempt to assess what impact this may have on the overall pooled effect.

We were unable to conduct within-trial subgroup analyses; all subgroups were between trials. This weakens the strength of the analyses. We conducted several subgroup analyses on a small number of trials, thereby increasing the risk of a chance finding. The potential explanation for heterogeneity was *post hoc* and therefore only hypothesis generating.

Although we conducted a thorough search of seven databases using a highly sensitive search strategy, we may have missed some publications. Although we did not detect any publication bias, we were unable to formally assess it because of the small number of trials included.

Conclusion

This systematic review suggests that educational programmes for carers of community dwelling patients with dementia have a protective effect on caregiver burden and a small effect on caregiver depression. However, it does not provide evidence for effect on QoL and number of transitions to long stay care. Assessment of QoL is a very important and clinically significant area. Standardisation of assessment of QoL would facilitate more robust comparison of interventions in future studies. Further rigorous trials are needed with longer follow-up time to assess whether the effect on burden is sustained in the longer term and whether it has an effect on other outcomes. Future studies should include a cost analysis of implementing educational programmes for caregivers in the home

versus the cost of institutional care. The review highlights the importance of selecting core outcome sets in caregiver trials in order to facilitate pooling of evidence.

Original publication

This review has not been submitted for publication in any other journal prior to this submission.

Conflict of interest

None declared.

Key points

- Educational programmes have a moderate effect on caregiver burden and a small effect on caregiver depression.
- There is insufficient evidence to assess the effect of educational programmes on QoL and number of transitions to long stay care.

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Appendix A: Search strategies

MEDLINE(R) (Ovid) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>
Search Strategy:

1. exp Dementia/ (107917)
2. "dement*" .ab,ti. (62448)
3. "alzheim*" .ab,ti. (79549)
4. 1 or 2 or 3 (148030)
5. exp Caregivers/ (18758)
6. (carer* or caregiver* or care giver*) .ab,ti. (34729)
7. 5 or 6 (41098)
8. (learn* or education* or information* or support* or psychoeducation* or psycho-education* or train*) .ab,ti. (2027024)
9. exp health education/ (127971)
10. education, nonprofessional/ (63)
11. 8 or 9 or 10 (2090252)
12. Caregivers/ed [education] (1715)
13. 7 and 11 (19476)
14. 13 or 12 (19877)

15. (randomized controlled trial or controlled clinical trial).pt. (418964)
16. (randomized or randomised or placebo or randomly or trial or groups).ab. (1663851)
17. 15 or 16 (1775048)
18. 4 and 14 and 17 (903)

PsycINFO <1806 to present>

Search Strategy:

1. exp alzheimer's disease/ (28166)
2. exp Dementia/ (46795)
3. (dement* or alzhem*).ti,ab. (59814)
4. 1 or 2 or 3 (61365)
5. education/ or exp client education/ or exp consumer education/or exp educational programs/ or exp psychoeducation/ or exp training/ (116278)
6. (learn* or education* or information* or support* or psychoeducation* or psycho-education* or train*).ti,ab. (1133607)
7. 5 or 6 (1151472)
8. exp caregivers/ or exp caregiver burden/ or exp elder care/ or exp home care/ (22877)
9. (carer* or caregiver* or care giver*).ti,ab. (31316)
10. 8 or 9 (39130)
11. 4 and 7 and 10 (3194)
12. limit 11 to "2000 treatment outcome/clinical trial" (97)

Embase <1980 to present>

Search Strategy:

1. exp dementia/ (202996)
2. (dement* or alzhem*).ti,ab. (157126)
3. 1 or 2 (228882)
4. exp caregiver/ (32997)
5. (caregiver* or carer* or care giver*).ti,ab. (46078)
6. 4 or 5 (55559)
7. education/ (277949)
8. exp health education/ (215234)
9. exp psychoeducation/ (2826)
10. (learn* or education* or information* or support* or psychoeducation* or psycho-education or train*).ti,ab. (2424806)
11. 7 or 8 or 9 or 10 (2666599)
12. exp crossover-procedure/ or exp double-blind procedure/ or exp randomized controlled trial/ or exp single-blind procedure/ (378044)
13. random* or factorial* or crossover* or cross over* or cross-over* or placebo* or (doubl* adj blind*) or (singl* adj blind*) or assign* or allocat* or volunteer*).ab,ti. (1195778)
14. 12 or 13 (1275096)
15. 3 and 6 and 11 and 14 (751)

CINAHL

- S1. (MH "Dementia + ") 37 539
- S2. AB dement* or alzhem* 16 484
- S3. S1 OR S2 41 289
- S4. (MH "Caregivers") 17 115
- S5. AB caregiver* or carer* or care giver* 21 103
- S6. S4 OR S5 31 104
- S7. (MH "Education, Nonprofessional + ") OR (MH "Psychoeducation") 92 697
- S8. AB education* or learn* or information* or support* or psychoeducation* or psycho-education* or train* 361 169
- S9. OR S8 427 840
- S10. S3 AND S6 AND S9 1987
- S11. AB randomised or randomized or clinical trial or control group or double-blind or randomized controlled trial or single-blind or controlled trial or random* or placebo* 196 785
- S12. (MH "Randomized Controlled Trials") OR (MH "Clinical Trials") 126 333
- S13. S11 OR S12 257 700
- S14. S10 AND S13 339

Cochrane

Search Strategy:

1. MeSH descriptor: [Dementia] explode all trees 3282
2. MeSH descriptor: [Alzheimer Disease] explode all trees 1930
3. (dement* or alzhem*):ti,ab,kw 6954
4. #1 or #2 or #3 7122
5. MeSH descriptor: [Caregivers] explode all trees 943
6. (caregiver* or carer* or care giver*):ti,ab,kw 2895
7. #5 or #6 2895
8. MeSH descriptor: [Health Education] explode all trees 8579
9. MeSH descriptor: [Education, Nonprofessional] explode all trees 11 429
10. (learn* or education* or information* or support* or psychoeducation* or psycho-education* or train*):ti,ab,kw 96 741
11. #8 or #9 or #10 97 522
12. (#4 and #7 and #11) in Clinical Trials 254

AgeLine

- S1. AB dement* or alzhem* 14 082
- S2. AB carer* or caregiver* or care giver* 9163
- S3. AB learn* or education* or information* or

support* or psychoeducation* or psycho-education* or train* 52 056

S4. AB randomised or randomized or clinical trial or control group or double-blind or randomized controlled trial or single-blind or controlled trial or random* or placebo* 6623

S5. S1 AND S2 AND S3 AND S4 223

ERIC

(dement* or alzheimer*) and (caregiver* or carer* or care and giver*) and (learn* or education* or information* or support* or psychoeducation* or psycho-education* or train*) and (randomised or randomized or clinical and trial or control and group or double-blind or randomised and controlled and trial or single-blind or controlled and trial or random* or placebo*)

Appendix B: Findings of included studies

Source	Outcomes	Findings
de Rotrou <i>et al.</i> , 2011	Carer Burden Zarit, Depression MADRS	Depression: No effect, $p = 0.14$ Carer burden: No effect, $p = 0.25$
Gavrilova <i>et al.</i> , 2009	Carer Burden Zarit, QoL WHOQOL-BREF	QoL: No significant effect for any domain (physical, psychological, social, environmental) Carer burden: Significant effect (Intervention group mean difference -2.6 ; control group mean difference 2.8 ; $p = 0.03$)

(Continues)

Appendix B. (Continued)

Source	Outcomes	Findings
Guerra <i>et al.</i> , 2011	Carer Burden Zarit, QoL WHOQOL-BREF	QoL: No effect on psychological and physical domains. Statistically insignificant trend for social ($p = 0.12$) and environment ($p = 0.08$) effect using adjusted values Carer burden: Significant effect (Intervention group mean difference -3.6 ; control group mean difference 0.3 ; $p < 0.001$)
Hepburn <i>et al.</i> , 2001	Carer Burden Zarit, depression CES-D	Depression: Significant effect, $p = 0.04$ Carer Burden: Significant effect, $p = 0.05$
Kurz <i>et al.</i> , 2010	QoL SF-36, depression MADRS, transition to long stay facility (numbers)	QoL: Significant effect for emotional role. No effect for social functioning and psychological domains. Transition to long stay facility: No effect (intervention group: 34/156, control group: 23/136), $p = 0.25$ Depression: No effect, $p = 0.25$
Martin-Carrasco <i>et al.</i> , 2009	Carer Burden Zarit, QoL SF - 36	QoL: Significant effect for physical role and functioning, general health, vitality, emotional role. Trend for social ($p = 0.06$). No effect for mental health Caregiver burden: Trend towards reduced burden ($p = 0.08$)
Pahlavanzadeh <i>et al.</i> , 2010	Carer Burden Zarit	Carer burden: Significant effect, $p < 0.001$