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Protocol for a systematic review: Home visits for prevention of impairment and death in elderly people[1]

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Background

According to the UN, in 2000 nearly 7% of people worldwide were aged 65 and over, whilst in Europe this population reached nearly 15% (WPP 2004). It is predicted that these numbers will more than double over the next half century and that the trend will be more pronounced in developed countries. The cost of hospitalisation, institutionalisation and social care for this increasingly elderly population has become a major societal concern in many developed countries. Cognitive and functional decline are common disabling features amongst this population making life difficult for the elderly themselves, often placing a burden of responsibility and stress on family and carers (Jones 1992, McKinlay 1995) and may lead to long-term hospital or institutional admission (Haupt 1993, Jette 1992).

Preventive home visits of persons aged 75 and over are part of government policy in many developed countries including the UK, Denmark, Switzerland, Japan and Australia. Home visits intend to prevent cognitive and functional impairment and prolong survival through primary prevention (e.g. early recognition of risk factors, provision of health information, risk reduction and safety promotion, identification of social isolation and loneliness), secondary prevention (e.g. detection of untreated/sub-optimally treated problems) and tertiary prevention (e.g. encouraging medication compliance and adherence to health advice; Fletcher 1998). However, other factors also may be important in mediating the effectiveness of preventive home visits including social support, demographic characteristics, initial comprehensive geriatric assessment and the professional experience of the home visitor.

Enabling older people to remain in their own homes has been at the foundation of many governments' policies for several years (Dept of Health 2001, Rostgaard 1998). It may be that preventive home visits increase the likelihood of independent living, thus leading to improved social functioning and mental health among elderly persons (Broese 1996, Pahor 1997). Since the majority of older people wish to remain living independently in their own homes for as long as possible (Dept of Health 2001, Rostgaard 1998), those who do so may experience a greater sense of well-being and quality of life.

Numerous randomised controlled trials have been conducted in this area with varying eligibility criteria. For example, some have included elderly people at high risk of institutionalisation while others have included people representative of the general elderly population. Some have included all people over 65 while others have focused on those over 75. Previous reviews and meta-analyses based on RCTs have suggested that home visits by health or social care professionals may have direct and indirect (e.g. economic) benefits (Elkan 2001, Stuck 2002, Van Haastreght 2000), but they reached different conclusions. Van Haastreght 2000 found very little clear evidence in favour of home visits and concluded that unless the effectiveness of visits could be improved, serious thought should be given to their discontinuation. Elkan 2001, on the other hand, found that home visiting programmes that offer health promotion and preventive care to older people can be effective in reducing both mortality and admission to institutional care. Stuck 2002 concluded that home visits to the elderly who are at lower risk of death and

which are based on multi-dimensional geriatric assessment with multiple follow-up visits, appear to be most effective. Furthermore, existing reviews have numerous methodological flaws. Van Haastreght 2000 used 'vote counting', overlooking sample size, effect size, clinical significance and methodological quality. Elkan 2001 may have compromised the detection of successful elements of home visits by including both studies of 'in-home preventive visits' and 'home-based' care co-ordination programmes for 'at risk' patients discharged from hospital.

Assessing the specific characteristics of effective home visits has been further hindered because of the multi-dimensional character of existing interventions. For example, some programmes have sought to prevent functional decline and mortality through fall prevention and the removal of hazards in the home. Others have provided assistive devices, promoted exercise, and offered comprehensive medical, psychosocial and nutritional interventions. Visits have been conducted by different health professionals including specialised nurses, social workers and physiotherapists over different periods of time and with different frequency. This has made it difficult to distinguish the active elements necessary for favourable outcomes from the total set of elements within any programme. This problem has been further compounded by many trials providing only general information on programme content, and little information on either programme integrity or patient compliance. Stuck 2002 has acknowledged the need for further meta-analyses and trials to clarify which components of home visits may be valuable and who is most likely to benefit.

This review will examine the evidence concerning preventive visits for the elderly and will attempt to identify moderators of intervention effects.

Objectives

To assess the effectiveness of preventive visits on cognitive and functional impairment, on quality of life and on mortality in older people (65+ years) without dementia and attempt to identify factors that may moderate effects through pre-specified subgroup analyses.

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and clustered RCTs will be considered for inclusion. Quasi-randomised studies and non-randomised studies will not be included.

There are many randomised studies of the effectiveness of preventive home visits for the elderly. The results of well-designed non-experimental evaluations sometimes differ from those of randomised trials (Deeks 2003), and no practical or ethical barriers preclude randomised trials of preventive home visits.

Types of participants

Eligible participants include persons aged 65 years and above, living independently (whether alone or with a partner). Where study authors indicate that more than half of the participants in a trial are persons with dementia, the trial will be excluded from the review.

Types of interventions

Visits at home by a health or social care professional aiming to prevent avoidable cognitive and functional decline and mortality in the elderly individual will be included. These may comprise 'usual' health visiting practice (e.g. surveillance /monitoring of compliance with medication or other interventions, social support, health promotion and prevention of ill health, co-ordination of community services, practical advice, referral to other services and counselling) or visits that include comprehensive geriatric assessment and result in specific recommendations to reduce, treat or prevent problems. Trials that evaluate follow-up home visits directly related to recent hospital discharge (e.g. to assess or attend a recently treated condition) will be excluded as these interventions are not preventive.

Types of outcome measures

Outcomes will include:

1) mortality,
2) quality of life (e.g. SF-36; Ware 1993),
3) cognitive function (e.g. Mini Mental Status Exam (MMSE; Folstein 1975),
4) physical function (e.g. Activities of Daily Living; Lawton 1982),
5) physical illness (e.g. incidence of injury or disease),
6) psychiatric illness (.e.g. Geriatric Depression Scale; Sheikh 1986).

The validity of outcome measures will be addressed in the table of excluded studies and the text (including references to specific validation studies).

Outcome intervals

Outcomes will be grouped by length of follow-up (e.g., post-intervention, 0-12 months, 12-24 months, etc.).

Search strategy for identification of studies

1) Electronic search

The following databases will be searched without language restriction for published and unpublished studies:

C2-SPECTR (The Campbell Collaboration's Social, Psychological, Educational and Criminological Trials Register)
CINAHL (Cumulative Index to Nursing and Allied Health Literature)
CENTRAL (Cochrane Central Register of Controlled Trials)
EMBASE
MEDLINE
PsycINFO
SIGLE search (System for Information on Grey Literature in Europe)

MEDLINE will be searched using the following terms (which will be adapted for other databases as needed):

1 clinical-trial in PT
2 randomized-controlled-trial in PT
3 controlled-clinical-trial in PT
4 randomi?ed in AB
5 placebo in AB
6 randomly in AB
7 trial in TI
8 "clinical trials"
9 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
10 animals in TG
11 humans in TG
12 #10 not (#10 and #11)
13 #9 not #12
14 "House-Calls"/ all subheadings
15 (home* or in-home* or domiciliary) near (visit* or support* or care or service*)
16 visit* near (nurse* or doctor* or physician* or volunteer* or health)
17 (preventive near (programme* or visit)
18 "health promotion*" or "health education" or "health screening*" or “geriatric assessment*” or “preventive assessment*”
19 #14 or #15 or #16 or #17 or #18
20 explode "Aged"/ all subheadings
21 #19 and #20
22 #21 and #13

2) Handsearches
Reference lists from previous reviews and from all included and excluded studies will be searched.

Relevant websites, including those maintained by users, governments, other agencies, and academics will be searched.

3) Personal communications
Appropriate government departments, non-governmental organisations, non-profit groups, advocacy groups, user groups, and experts in the field will be contacted and listed in an appendix to the review. These approaches and any replies will be documented by the authors.

The reviewers will contact authors of all included and excluded studies to request details of ongoing and unpublished studies.

Methods of the review

Trial selection strategy

Two authors (JB and PM) will review all titles and abstracts to eliminate articles that are not related to preventive home visits. Remaining titles and abstracts will be independently screened by two authors (JB and PM). Complete copies of evaluation studies related to preventive home visits will be collected either by JB or by research staff at the Oxford Centre for Evidence-Based Intervention. . Two reviewers will independently determine if each study identified meets the stated inclusion criteria (JB and PM). Authors will be contacted if further information could resolve initial disagreements about inclusion. Remaining disagreements will be discussed and resolved with the third reviewer (EMW). A flowchart of the process of trial selection will be made in accordance with the QUOROM statement (Moher 1999).

Data management

Data extraction will be conducted independently by two of the authors using a specially developed data extraction form (Appendix A). Differences will be reconciled through discussion and consultation with a third author. All extracted data will be presented in the included studies tables and in additional tables as necessary.

Data collection
For all trial arms, the following data will be collected:
1) Descriptive data, including age, socioeconomic status, race/ethnicity and gender;
2) Content and delivery of the intervention including type and focus of visits and professional qualifications of visitors;
3) Frequency and duration of intervention; and
4) Outcome measures listed above.

The following data will be collected for all studies:
1) Programme differentiation (Dane 1998, MRC 2000), including crossover between groups and the differences between the interventions received; and
2) Context.

Quality assessment
Two reviewers will independently assign each included study to a quality category (Higgins 2005) where:
(A) indicates adequate concealment of the allocation (e.g. use of consecutively numbered, sealed, opaque envelopes);
(B) indicates uncertainty about whether the allocation was adequately concealed (e.g. the method of concealment is not described);
(C) indicates that the allocation was definitely not adequately concealed (e.g. open random number lists);
(D) indicates that random allocation was not used.

Studies in categories A and B will be considered for inclusion in the review and meta-analyses. In studies classified as 'B' (unclear), the pre-treatment assessment and the allocation of participants will be described in the description of studies to identify differences between intervention and control groups that may have existed at baseline.

Existing scales for measuring the quality of controlled trials have not been properly developed, are not well-validated and are known to give differing (even opposing) ratings of trial quality in systematic reviews (Moher 1995). At present, evidence indicates that 'scales should generally not be used to identify trials of apparent low quality or high quality in a given systematic review. Rather, the relevant methodological aspects should be identified a priori and assessed individually' (Juni 2001). Where the two independent sets of codes of quality assessment do not agree, disagreements will be discussed and resolved with a third reviewer.

All trials will be assessed for internal validity. The following components will be described in the description of studies:
1) Allocation bias (Might allocation have been related to outcomes or the interventions received?);
2) Performance bias (Could the services provided have been influenced by something other than the interventions being compared?);
3) Detection bias (Could the outcomes have been influenced by anything other than the constructs of interest, including biased assessment or the influence of exposure on detection?);
4) Report bias (Were the outcomes, measures and analyses selected a priori and reported completely? Were participants biased in their recall or response? (Delgado-Rodriguez 2004, Juni 2001); and
5) Outcome validity (Were the outcome measures objective or validated for the relevant population?).

Multiple arms
All eligible outcome measures for all trial arms will be reported in the review.

If two or more eligible intervention groups are compared to an eligible control, thus requiring that the reviewers choose a single intervention group for comparison or inclusion in a meta-analysis, the group receiving the most comprehensive or intense intervention will be selected.

If a single eligible intervention group is compared to multiple eligible control groups, no-treatment or treatment-as-usual controls will be chosen over other groups for comparison and inclusion in meta-analyses.

Multiple measures
When a single study provides multiple measures of the same outcome, a standardised mean difference (SMD) or relative risk (RR) will be calculated for each outcome measure. For the purposes of meta-analysis, an average effect size (SMD or RR) will be calculated.

Missing data
In the first instance, the primary author of each included study will be contacted by JB to supply any unreported data (e.g. group means and standard deviations, details of dropouts, details of interventions received by the control group). For trials reporting outcomes only for participants completing the trial, the primary author will be contacted and asked to provide additional information to permit intention-to-treat analyses. If no missing data concerning attrition are obtainable, the analyses and review will report the number of participants completing the trial.

Studies in which participants are analysed as members of the groups to which they were originally assigned (intention-to-treat analysis), studies that include only those participants who were willing or able to provide data (available-case analysis), and studies that analyse participants who adhered to the study's design (per-protocol analysis; Higgins 2005) will be analysed separately.

Data synthesis

Outcome data
RevMan 4.2 will be used to perform the following calculations.

Within studies, RRs and 95% confidence intervals (CIs) will be calculated for comparisons of dichotomous outcome measures (e.g., mortality). SMDs and 95% CIs will be calculated for comparisons of continuous outcome measures (e.g., quality of life scales) when means and standard deviations or complete significance testing statistics are available.

Meta-analyses may be conducted to combine comparable outcome measures across studies. All overall effects will be calculated using inverse variance methods. Random-

effects models will be used because studies may include somewhat different treatments or populations. Dichotomous outcome measures may be combined by calculating an overall RR and 95% CI. Continuous outcome measures (including scale data) may be combined by calculating an overall SMD and 95% CI using Hedges *g* (Higgins 2005).

When trials use clustered randomisation, we expect results to be presented with proper controls for clustering (robust standard errors or hierarchical linear models). If it is not clear whether a cluster-randomised trial used appropriate controls for clustering (autocorrelated data), the primary author will be contacted for additional information. If appropriate controls were not used, individual participant data sets will be requested. These data sets will be re-analysed using multilevel models which control for clustering; effect estimates and standard errors will then be meta-analysed in RevMan using the generic inverse variance method (Higgins 2005). If appropriate controls were not used and it is impossible to obtain the full set of individual participant data, we will control for clustering using the procedures outlined in Adams (2004) and Higgins (2005). That is, when outcome measures are dichotomous, the number of events and number of participants per trial arm will be divided by the design effect [1 + (1 - m) * r], where m is the average cluster size and r is the intra-cluster correlation coefficient (ICC). When outcome measures are continuous, the number of participants per trial arm will be divided by the design effect, while leaving the mean values unchanged. The average cluster size (m) will be calculated using the details provided by each study (total N and number of clusters). To determine the ICC, the reviewers will first seek estimates in the primary trials on a study-by-study basis. However, if these values are not reported, the reviewers will seek external estimates of the ICC that are appropriate to each trial context and average cluster size (Higgins 2005, Ukoumunne 1999). In this case, statistical guidance will be sought from the C2 Methods Group and external experts. If there is insufficient information to control for clustering, outcome data from cluster-randomised trials will be entered in RevMan using individuals as the units of analysis and then sensitivity analysis will be used to assess the potential biasing effects of clustered trials that did not provide adequate controls for clustering.

Homogeneity

The consistency of results will be assessed using the I^2 statistic (Higgins 2002, Higgins 2003). If there is evidence of heterogeneity (*Q*-statistic <0.01 coupled with an I^2 value of 25% or greater), the authors will consider sources according to pre-specified subgroup analyses and sensitivity analyses (below) but will not calculate an overall estimate of effect size.

Subgroup analysis

Large numbers of subgroups may lead to misleading conclusions and are best kept to a minimum (Counsell 1994, Oxman 1992, Yusuf 1991). If possible, this review will include subgroup analyses based on:

1) the professional group from which the home visitors come (e.g. social workers, geriatricians, nurses);

2) age of participant (<75 years; > or = 75 years);
3) number of visits.

The ANOVA analog will be performed to determine whether differences between subgroups are significant. Meta-regression analysis will be used to assess potential effects of pre-specified moderators if the power to detect potentially meaningful differences (differences in ES of at least 0.1) is greater than or equal to 0.8 (Cohen's standard) and the correlation between moderators in the analysis is less than |0.4|.

Assessment of bias
To investigate the possibility of bias, including publication bias, funnel plots will be drawn (Deeks 2005, Egger 1997, Sterne 2001). In the event of asymmetry, the reviewers will seek input from methodologists, including the Cochrane and Campbell Collaboration Methods Groups, on appropriate analyses.

Graphs
When meta-analyses are performed, data will be entered into RevMan 4.2.

Qualitative data
Qualitative data from included studies may be included to better understand the design and delivery of interventions, uptake by participants, and context.

Plans for updating the review
If funding is available, the lead author plans to run a new search every three years and update the review if new studies are found.

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Potential conflict of interest

The reviewers have no known conflicts of interest.

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Study:

Author queries:

Location:
Other context data:
Funding source:

Number randomised: total (experimental, control)
Unit of randomisation:
Method of randomisation:
Allocation concealment (described and rating A-C):
Threats to internal validity (bias: allocation, performance, detection, report):

Notes of recruitment, inclusion & exclusion criteria, screening:

Control group:
Other arms:

Age range: experimental, control
Mean age (sd): experimental, control
% Female: % experimental, % control
Living arrangement (e.g. alone): experimental, control
Socioeconomic status: experimental, control
Ethnicity:

Visitors' professional group:
Focus/ description of visit:
Number of visits:
Duration of intervention:

Fidelity (including participant compliance and differentiation between groups):

Notes:

Mortality

Measure	Time since randomisation	Survivors	Number in analysis	ITT?	Notes, inc outcome validity
		Exp: Con:	Exp: Con:		

Other dropout

Number	Time since randomisation	Reason	Notes, inc outcome validity
Exp: Con:			

Institutionalisation / Long-term hospitalisation

Measure	Source (e.g. self-report, records)	Time since randomisation	Outcome data	Unaccounted survivors	ITT?	Notes, inc validity
			Exp: Con:	Exp: Con:		

Falls

Measure	Source (e.g. self-report, records)	Time since randomisation	Outcome data	# in analysis/ # survivors	ITT?	Notes, inc validity
			Exp: Con:	Exp: Con:		

Quality of life

Measure	Source (e.g. self-report, records)	Time since randomisation	Outcome data	# in analysis/ # survivors	ITT?	Notes, inc validity
			Exp: Con:	Exp: Con:		

Cognitive / Physical function

Measure	Source (e.g. self-report, records)	Time since randomisation	Outcome data	# in analysis/ # survivors	ITT?	Notes, inc validity
			Exp: Con:	Exp: Con:		

Psychiatric / Physical illness

Measure	Source (e.g. self-report, records)	Time since randomisation	Outcome data	# in analysis/ # survivors	ITT?	Notes, inc validity
			Exp: Con:	Exp: Con:		

Other outcomes (e.g. costs, satisfaction, social function)

Measure	Source (e.g. self-report, records)	Time since randomisation	Outcome data	# in analysis/ # survivors	ITT?	Notes, inc validity
			Exp: Con:	Exp: Con:		