Physical activity programs for persons with dementia (Protocol)

Forbes DA, Forbes SC, Markle-Reid, M, Morgan DG, Taylor BJ, Wood J

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:
1.To evaluate the effects of physical activity programs on function (e.g., activities of daily [ADLs], physical function), cognition, mood, behaviour, and mortality in older persons with dementia.
2.To evaluate these effects on their unpaid caregiver's health, quality of life, and mortality.
3.To evaluate the indirect costs (e.g., number and amount of lost wages by caregiver(s) and direct costs (e.g., use of supportive services, medications, supplies) for the person with dementia and their unpaid caregiver.
4. To make recommendations to health care providers, consumers, and researchers on the effectiveness of physical activity programs in managing the symptoms of dementia in older persons with dementia.

BACKGROUND

With the longer life expectancy and continued growth of the older population, greater numbers of persons will be affected with dementia, impacting their ability to function independently in their communities. In addition, chronic conditions, such as dementia, are the leading causes of death among seniors (Wilkins 2006). Eight percent of persons 65 years of age and older and 35 percent of those over the age of 85 have dementia (CSHAWG 1994a). Half of those with dementia live in the community and over 90% are cared for by family members or friends (CSHAWG 1994a). Advanced dementia results in extreme functional disability, behavioral problems, and dependence (Chappell 1996), and unrelenting demands on unpaid caregivers (Markle-Reid 2001). Compared to those caring for cognitively intact elderly, caregivers of a family member with dementia are more likely to experience social isolation, chronic health problems, and depression (CSHAWG 1994b). The health service costs (Ostbye 1994) will rise substantially if unpaid caregivers are not adequately supported when caring for those with dementia.

Exercise has been shown to have multiple positive effects with older adults, including improved functional ability (Larowski 1999), cognition (Yaffe 2001) and physical and mental health (Penninx 2002; Taylor 2004). Several longitudinal cohort studies in older adults have demonstrated that physical activity is associated with reduced cognitive decline two years later (Lytle 2004) and reduced risk of developing dementia five years later (Laurin 2001). However, Wilson 2002 failed to find a protective effect of physical activity on cognitive decline and on incidence of dementia. A meta-analysis that included 18 randomized controlled trials (RCTs) examined the impact of physical exercise on cognitive function in healthy older adults. Moderate effect sizes for the impact of exercise training on global cognitive scores with a larger effect on tasks measuring executive control were reported (Colcombe 2003).

There is a growing body of research suggesting that some risk factors for heart disease and stroke are also associated with a greater risk of developing Alzheimer disease and related dementias (Chertkow 2006; Feldman 2006; Hofman 1997; Kalmijn 2000; Sparks 1997). These findings suggest that exercise training designed to prevent and manage cardiovascular disease and related conditions such as diabetes and hypertension may also be effective in the prevention and management of dementia. A meta-analysis on the effects of exercise training on older persons with cognitive impairment and dementia included 30 RCTs (Heyn 2004); how-

ever, not all studies targeted persons with dementia. This meta-analysis revealed that exercise training increased fitness, physical function, cognition and positive behaviour in these individuals (Heyn 2004). A recent RCT that specifically targeted persons with Alzheimer disease revealed that a simple exercise program consisting of walking, strength, balance, and flexibility training one hour twice a week for one year led to a significantly slower decline in activities of daily living when compared to routine care but no effect was observed in behavioural disturbances or depression (Rolland 2007 in press). Other studies have examined the effect of a combination of endurance (aerobic) activities, strength, balance and flexibility training (e.g., Teri 2003; Alessi 1999) while others focused on a single activity (e.g., walking program, MacRae 1996)

There are potentially immense public health benefits to decreasing the risk of dementia and slowing the progression of the dementia. However, further research is needed to assess the optimal exercise training modalities in older adults with dementia particularly in terms of frequency, intensity, and duration (Chertkow 2007 in press). A systematic review will be conducted that incorporates meta-analysis, if appropriate, to determine the effects of activity programs on function, cognition, mood, behaviour and mortality in older persons with dementia, caregiver quality of life and mortality, and costs. For example, direct costs may include out-of-pocket expenses incurred by the person with dementia and/or their unpaid caregiver for respite care, assistance with meal preparation, medications, incontinence supplies, travel expenses to receive medical assessments and care etc. and indirect costs may include those related to caregiver(s) reducing their hours of employment, delaying a promotion etc due to the need to fulfil their caregiving role.

OBJECTIVES

1.To evaluate the effects of physical activity programs on function (e.g., activities of daily [ADLs], physical function), cognition, mood, behaviour, and mortality in older persons with dementia.
2.To evaluate these effects on their unpaid caregiver's health, quality of life, and mortality.
3.To evaluate the indirect costs (e.g., number and amount of lost wages by caregiver(s) and direct costs (e.g., use of supportive services, medications, supplies) for the person with dementia and their unpaid caregiver.
4. To make recommendations to health care providers, consumers, and researchers on the effectiveness of physical activity programs in managing the symptoms of dementia in older persons with dementia.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomized controlled trials (RCTs) in which older adults with dementia are allocated to either a physical activity program or regular care (control group). Although parallel group trials are preferred, crossover trials will be included but only data from the first treatment phase (prior to the crossover) will be included. Non-blinded studies will be included in the review as it may be unrealistic to expect blinding of the participants and those who conduct the physical activity programs. The outcome assessors should be blinded to treatment allocation.

Types of participants

The participants will be older persons (65 years and older) who reside in the community or in a long-term care facility and who are diagnosed as having dementia using accepted criteria such as the Diagnostic and Statistical Manual of Mental Disorders (DSM-III-R, DSM-IV; APA 1995), the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (McKhann 1984) or ICD-10 (WHO 1992). The types of dementia and levels of severity will be described and if possible subgroup analyses will be conducted to determine their effects on the outcome measures.

Types of intervention

Interventions include any exercise training or physical activity program (aerobic exercise and/or resistance training) offered over any length of time with the aim to improve function, cognition, mood, behaviour, and mortality in older persons with dementia and/or caregiver health related quality of life, to decrease caregiver burden, mortality, and/or cost incurred by the person with dementia or their unpaid caregiver. We intend to measure the effect of physical activity; hence studies will be included where the only difference between groups is the exercise intervention. The types, frequencies, intensities, duration, and settings of the exercise programs will be described and if possible, subgroup analyses will be conducted to determine their effects on the outcomes of interest. The comparison group will receive regular/normal care.

Types of outcome measures

The primary outcomes are related to the person with dementia: function (e.g., activities of daily [ADLs], physical function), cognition, mood, behaviour, medication use (e.g., psychotropic drugs), and mortality. Secondary outcomes are related to the unpaid caregiver(s): burden, quality of life, and mortality. Direct costs (e.g., use of supportive services, medications, supplies) and indirect costs (e.g., number and amount of lost wages by caregiver(s) will also be examined. Measures from dichotomous and continuous scales will be accepted and follow-up measures over time will be included.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Dementia and Cognitive Improvement Group methods used in reviews.

The Cochrane Dementia Group's Specialized Register will be searched using the terms "exercise*" and "physical activity*". This Register contains records from MEDLINE, EMBASE, CINAHL, PsycINFO and many trials databases and is updated regularly.
Reference lists of retrieved articles will be examined for additional trials.

METHODS OF THE REVIEW

SELECTION OF TRIALS

Titles and abstracts of citations obtained from the search will be examined by one author and obviously irrelevant articles discarded. At this stage the author will be overly inclusive: any article that suggests a relevant randomized controlled trial will be retrieved for further assessment. Two authors will independently assess retrieved articles for inclusion in the review according to the criteria above. Disagreements will be resolved by discussion, or if necessary referred to a third author.

ASSESSMENT OF METHODOLOGICAL QUALITY

Methodological quality criteria were developed with input from all of the authors based on The Cochrane Handbook for Systematic Reviews of Interventions, version 4.2.6 (Higgins 2006). Two authors will independently assess and score the studies according to the following criteria that reflect the adequacy of the randomization process. If the description of the randomization process is unclear or missing, the original author of the study will be contacted in an attempt to retrieve the required information.

A. Adequate

"centralised allocation by a central office unaware of participant characteristics
"pre-numbered or coded identical containers which are administered serially to participants
"on-site computer system combined with allocations kept in a locked unreadable computer file that can be accessed only after the characteristics of an enrolled participant have been entered
"sequentially numbered, sealed, opaque envelopes
"other approaches that ensure adequate concealment.

B. Unclear

"study used "list" or "tables" to allocate assignments
"use of "envelopes" or "sealed envelopes"
"simply stating that the study was randomized with no further details

C. Inadequate

"by using case record numbers, dates of birth, alternation, date of referral, and other similar approaches that are transparent before allocation
"use of any other system in which allocation can be known in advance such as open list of random numbers.

D. Allocation concealment not used

Because empirical research has shown that lack of adequate allocation concealment is associated with bias (Moher 1998), only those studies in categories A and B will be included in the review. Other elements of study quality, although not scored, will be assessed by two authors independently and reported:
""blinding" of participants, those providing the physical activity, and outcome assessors to the nature of the allocated group.
"level of participant drop-out at the follow-up stage of the study.
"equal treatment of both intervention and control participants in all respects other than the delivery of the physical activity.
Since at least two empirical studies have failed to demonstrate a relationship between blinding of outcome assessment and study results, perhaps due to inadequacies in the reporting of studies (Reitman 1988) and since attrition after allocation has not been found to be consistently related to bias (Schulz 1995), the results of these criteria will be reported but not used as criteria for exclusion of studies from the review.

DATA EXTRACTION and ANALYSIS

Data will be extracted from published reports or requested from the original first author when necessary. Summary statistics will be required for each trial and each outcome. For continuous data, the effect measure will be the weighted mean difference (WMD) when the pooled trials use the same rating scale or test to assess an outcome or the standardised difference in means (SMD), which is the absolute mean difference divided by the standard deviation, when the pooled trials use different rating scales or tests. Accordingly, the mean change from baseline, the standard deviation of the mean change, and the number of patients for each treatment group at each assessment will be extracted. Where changes from baseline are not reported, the mean, standard deviation and the number of participants for each group at each time point will be extracted, if available.
For dichotomous data, the effect measure will be odds ratio (OR). The numbers in each group (exercise or regular care) and the numbers experiencing the outcome of interest will be sought and recorded.

The amount and kind of missing data related to participants' drop-out that cannot be retrieved from the original authors will be described in the Characteristics of Included Studies Table and the impact discussed. The potential impact of the missing data on the results will depend on the extent of missing data, the pooled estimate of the treatment effect and the variability of the outcomes. Variation in the degree of missing data may also be considered as a potential source of heterogeneity. Intention-to-treat analyses will be conducted by imputing outcomes for the missing participants

using the last observation carried forward approach. Recognizing that statistical analysis cannot reliably compensate for missing data (Unnebrink 2001), the impact of any assumption will be assessed by trying more than one method as a sensitivity analysis. For example, for dichotomous data, it will first be assumed that all missing participants in the first group incurred the event and those in the second group did not, after which the opposite will be assumed. When missing data are common, these worst-case/best-case scenarios will cover a very wide range of possible treatment effects and thus the analysis will not be very informative. However, when missing data are not common and this procedure is done across all trials in the review with little impact on the results, it can be concluded that the missing data will not affect the outcome of the review.

Only studies that demonstrate clinical homogeneity (e.g., studies that test similar aerobic activity programs and examine similar outcome measures) will be considered potentially appropriate for meta-analysis. A test for statistical heterogeneity (a consequence of clinical and/or methodological diversity among studies) will then be performed using I2. This is a useful statistic for quantifying inconsistency (I2 = [(Q - df)/Q] x 100%, where Q is the chi-squared statistic and df is its degrees of freedom; Higgins 2003; Higgins 2002). This describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance). A value greater than 50% may be considered substantial heterogeneity. If the value is less than 50%, the overall estimate from a fixed effects model will be presented. If, however, there is evidence of heterogeneity of the treatment effect between trials then only homogeneous results will be pooled, or a random-effects model will be used. In this case the confidence intervals would be broader than those of a fixed-effects model.

Depending on availability of sufficient data, the following subgroup analyses will be undertaken:
Disease type:
- Alzheimer disease
- vascular dementia
- mixed Alzheimer disease and vascular dementia
- unclassified or other dementia
Severity of dementia at baseline:
- mild (MMSE > 17-26 or similar scale) (Hogan 2007 in press)
- moderate (MMSE 10 to 17 or similar scale (Hogan 2007 in press)
- severe (MMSE < 10 or similar scale) (Feldman 2005)
Type of aerobic physical activity, example:
- walking program
- dancing
Frequency of physical activity program:
- < 3 times per week
- > 3 times per week
Duration of physical activity program:
- < 12 weeks
- > 12 weeks
Intensity of physical activity program
- low-intensity
- moderate-intensity
- high-intensity
Setting of physical activity program
- institution
- home
Sensitivity analyses will be performed with regard to imputation of missing dichotomous data:
- assuming missing outcomes were less favourable
- assuming missing outcomes were more favourable
- analysis as presented

POTENTIAL CONFLICT OF INTEREST

None known.

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COVER SHEET

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What's New	Information not supplied by author
Contact address	Prof Dorothy Forbes Associate Professor H33 Health Sciences Addition, School of Nursing University of Western Ontario

London
Ontario
N6G 5L3
CANADA
E-mail: dforbes6@uwo.ca
Tel: 519-661-2111
Fax: 519-661-3928

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