A systematic literature review of the effectiveness of non-pharmacological interventions to prevent wandering in dementia and evaluation of the ethical implications and acceptability of their use

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A systematic literature review of the effectiveness of non-pharmacological interventions to prevent wandering in dementia and evaluation of the ethical implications and acceptability of their use

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NHS R&D HTA Programme

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The research reported in this monograph was commissioned by the HTA Programme as project number 03/16/04. The contractual start date was in March 2004. The draft report began editorial review in May 2005 and was accepted for publication in December 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

A systematic literature review of the effectiveness of non-pharmacological interventions to prevent wandering in dementia and evaluation of the ethical implications and acceptability of their use

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Objectives: To determine the effectiveness and cost-effectiveness of non-pharmacological interventions (excluding subjective barriers) in the prevention of wandering in people with dementia, in comparison with usual care, and to evaluate through the review and a qualitative study the acceptability to stakeholders of such interventions and identify ethical issues associated with their use.

Data sources: Major electronic databases were searched up until 31 March 2005. Specialists in the field.

Review methods: Selected studies were assessed and analysed. The results of two of the efficacy studies that used similar interventions, designs and outcome measures were pooled in a meta-analysis; results for other studies which reported standard deviations were presented in a forest plot. Owing to a lack of cost-effectiveness data, a modelling exercise could not be performed. Four focus groups were carried out with relevant stakeholders ($n = 19$) including people with dementia and formal and lay carers to explore ethical and acceptability issues in greater depth. Transcripts were coded independently by two reviewers to develop a coding frame. Analysis was via a thematic framework approach.

Results: Ten studies met the inclusion criteria (multi-sensory environment, three; music therapy, one; exercise, one; special care units, two; aromatherapy, two; behavioural intervention, one). There was no robust evidence to recommend any non-pharmacological intervention to reduce wandering in dementia. There was some evidence, albeit of poor quality, for the effectiveness of exercise and multi-sensory environment. There were no relevant studies to determine the cost-effectiveness of the interventions. Findings from the narrative review and focus groups on acceptability and ethical issues were comparable. Exercise and distraction therapies were the most acceptable interventions and raised no ethical concerns. All other interventions were considered acceptable except for physical restraints, which were considered unacceptable. Considerable ethical concerns exist with the use of electronic tagging and tracking devices and physical barriers. Existing literature ignores the perspectives of people with dementia. The small number of participants with dementia expressed caution regarding the use of unfamiliar technology. Balancing risk and risk assessment was an important theme for all carers in the management of wandering.

Conclusions: There is no robust evidence so far to recommend the use of any non-pharmacological intervention to reduce or prevent wandering in people with dementia. High-quality studies, preferably randomised controlled trials, are needed to determine the clinical and cost-effectiveness of non-pharmacological interventions that allow safe wandering and are considered practically and ethically acceptable by carers and people with dementia. Large-scale, long-term cohort studies are needed to evaluate the morbidity and mortality associated with wandering in dementia for people both in the community and in residential care. Such data would inform future long-term cost-effectiveness studies.

Contents

Glossary and list of abbreviations

Technical terms and abbreviations are used throughout this report. The meaning is usually clear from the context, but a glossary is provided for the non-specialist reader. In some cases, usage differs in the literature, but the term has a constant meaning throughout this review.

Glossary

ABC Approach   A behavioural approach used with people with dementia who wander which involves the assessment of the Antecedents, Behaviour and Consequences of their wandering.

Beneficence   A key principle in medical ethics; the duty to do good and act in the best interests of a person.

Buxton chair   A chair that is used to restrain patients and restrict their movements. It can be tilted backwards to prevent attempts to leave and also has a table which can be locked across the patient's lap.

Cocoon   A device like a sleeping bag, into which people can be zipped or fastened, which is then difficult to get out of without assistance.

Cognitive behavioural therapy   A combination of cognitive therapy, which examines unwanted thoughts, attitudes and beliefs, and behavioural therapy, which focuses on behaviour in response to those thoughts.

Multi-sensory environment (or Snoezelen)
This term refers to multi-sensory stimulation using unpatterned, non-sequential visual and auditory stimulation and a non-directive enabling approach by keyworkers.

Neuroleptic drugs   Drugs which have a tranquilising effect without impairing consciousness; also known as antipsychotic drugs.

Non-maleficence   A key principle in medical ethics; the duty to do no harm to a person.

Reality orientation   Behavioural therapy using the presentation of orientation information (e.g. time, place and person related).

Special care unit   A dedicated nursing unit that provides enhanced care and a specialised programme of activities for patients with a diagnosis of Alzheimer's disease or a related disorder.

Sundowning   Refers to wandering behaviour occurring in the evening and during the night in people with dementia.

Tethers   A strap used for tying patients to a bed or a chair.

Wandering   The term wandering refers to a complex collection of different behavioural abnormalities in dementia including checking; pottering; aimless walking; walking with inappropriate purpose; walking with appropriate purpose but inappropriate frequency; excessive activity; night-time walking; brought back home and attempts to leave home.

List of abbreviations

ABC	antecedents, behaviour and consequences
AD	Alzheimer's disease
ADL	activities of daily living
CDR	Clinical Dementia Rating scale
CHSR	Centre for Health Services Research
CI	confidence interval
CMAI	Cohen Mansfield Agitation Inventory
COBRA	Caretaker Obstreperous Behavior Rating Assessment scale. A behaviour scale which collects information about the frequency and severity of 30 problem behaviours associated with dementia, including wandering
DSM	Diagnostic and Standard Manual for mental disorders
GIP	Gedragsobservatieschaal voor de Intramurale Psychogeriatric. Dutch behaviour observation scale for intramural psychogeriatrics
GREG	Guideline Recommendation and Evidence Grading. A grading method for clinical guidelines
ICC	intracluster coefficient
ICD	International Classification of psychiatric Diseases
IIR	Individual Incident Record. An outcome measure to record a number of events including wandering behaviour
MDS-NH	Minimum Data Set instrument for Nursing Homes. An outcome measurement scale which includes items about behavioural problems including wandering
MID	multi-infarct dementia
MMSE	Mini Mental State Examination. Cognitive test
MRC CFAS	Medical Research Council Cognitive Function and Ageing Study
NHS CRD	National Health Service Centre for Reviews and Dissemination
NPI	NeuroPsychiatric Inventory. A behavioural scale which assesses ten behavioural disturbances occurring in dementia patients including aberrant motor activity (defined as purposeless pacing)
NUD*IST	Non-numeric Unstructured Data Index Searching and Theorising. A qualitative software program
OBS	Organic Brain Syndrome scale. A rating scale for the evaluation of confusional states and other organic brain syndromes
RA	research associate
RCT	randomised controlled trial
RR	relative risk
SD	standard deviation

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Background

Wandering occurs in around 15–60% of people with dementia. It can be beneficial, providing exercise and improving circulation, but may be problematic to both people with dementia and their carers, causing physical harm, emotional distress and early institutionalisation. Non-pharmacological interventions are recommended, but there is limited evidence for their effectiveness and ethical concerns exist around some. This review considers the following non-pharmacological interventions: physical barriers/restraints, electronic devices (tagging and tracking), distraction therapies (music, walking/exercise), sensory therapies (massage, aromatherapy, multi-sensory environments), behavioural therapies, carer interventions and environmental modifications.

Objectives

The objectives were to determine, through a systematic review, the effectiveness and cost-effectiveness of non-pharmacological interventions (excluding subjective barriers) in the prevention of wandering in people with dementia, in comparison with usual care, and to evaluate through the review and a qualitative study the acceptability to stakeholders of such interventions and identify ethical issues associated with their use.

Methods

Systematic review
Data sources
- Electronic searches including the Cochrane Library, MEDLINE, EMBASE, Central CINAHL, Social Science Citation Index, Science Citation Index, PsycINFO, ADEAR, National Research Register, ETHX database, Bioethicsweb.
- Grey literature: ISTP, ZETOC.
- Handsearching of relevant journals: *Journal of Dementia Care* (1999–2004), *Dementia* (2002–4).
- Personal contact with specialists in the field.

Data searching continued up until 31 March 2005.

Study selection
Studies to evaluate the effectiveness of interventions included randomised controlled trials (RCTs), non-randomised controlled trials, controlled before-and-after studies, cohort studies (both prospective and retrospective) and case–control studies (both prospective and retrospective).

Studies to evaluate cost-effectiveness of interventions included those costing the intervention strategies or wandering behaviour and full economic evaluations assessing the intervention strategies.

Studies to evaluate acceptability/ethical issues included surveys of opinion, qualitative studies and discussion papers.

Studies could be published in any language.

Included studies could take place in any care environment and involved participants with dementia (DSM or ICD diagnostic criteria) and acquired cognitive impairment. Primary outcome measures included any measure of wandering behaviour.

Data extraction
Checklists for each study were completed independently by two reviewers. For the effectiveness review, data extracted included details of participants, setting, methodology and results/relevant data; for the acceptability/ethics review, narrative and empirical data were extracted.

Data synthesis
The results of two of the efficacy studies which used similar interventions, designs and outcome measures were pooled in a meta-analysis; results for other studies which reported standard deviations were presented in a forest plot. Owing to a lack of cost-effectiveness data, a modelling exercise could not be performed.

Qualitative study
Four focus groups were carried out with relevant stakeholders ($n = 19$) including people with dementia and formal and lay carers to explore ethical and acceptability issues in greater depth. Transcripts were coded independently by two reviewers to develop a coding frame. Analysis was via a thematic framework approach.

Results

Effectiveness

Ten studies met the inclusion criteria (multi-sensory environment, three; music therapy, one; exercise, one; special care units, two; aromatherapy, two; behavioural intervention, one). There was no robust evidence to recommend any non-pharmacological intervention to reduce wandering in dementia. There was some evidence, albeit of poor quality, for the effectiveness of exercise and multi-sensory environment.

Cost-effectiveness

There were no relevant studies to determine the cost-effectiveness of the interventions.

Acceptability/ethical issues

Findings from the narrative review and focus groups were comparable. Exercise and distraction therapies were the most acceptable interventions and raised no ethical concerns. All other interventions were considered acceptable except for physical restraints, which were considered unacceptable. Considerable ethical concerns exist with the use of electronic tagging and tracking devices and physical barriers.

Existing literature ignores the perspectives of people with dementia. The small number of participants with dementia expressed caution regarding the use of unfamiliar technology. Balancing risk and risk assessment was an important theme for all carers in the management of wandering.

Conclusions

Implications for healthcare

There is no robust evidence to make any reliable recommendations for clinical practice.

Recommendations for research

The authors recommend the following research:

* High-quality studies, preferably RCTs, to determine the clinical effectiveness and cost-effectiveness of non-pharmacological interventions that allow safe wandering and are considered practically and ethically acceptable by carers and people with dementia. Such interventions include walking/exercise, music therapy (most acceptable), aromatherapy, massage, multi-sensory environments and environmental modifications/design (acceptable).
* Large-scale, long-term cohort studies to evaluate the morbidity and mortality associated with wandering in dementia for people both in the community and in residential care. Such data would inform future long-term cost-effectiveness studies.

The diversity of behaviours encompassed by the term 'wandering' should be acknowledged, with future studies measuring explicit outcomes which reflect:

* the consequences of wandering, for example successful elopement and getting lost
* the physical safety of the person with dementia (e.g. number and nature of physical injuries, number of hospital admissions)
* participant-centred outcomes that reflect the desired quality of life for both people with dementia and their carers, and also the acceptability of the intervention.

The views of people with dementia on the acceptability of non-pharmacological interventions to reduce wandering should be determined. This is particularly relevant for the use of assistive technologies in wandering. As the rapid development of relevant assistive technologies allows for a more diverse and sensitive range of electronic devices, research into users' views of their acceptability and feasibility should precede expensive and complex quantitative studies to evaluate their effectiveness.

There is a need to explore in greater depth the process of risk assessment and management by carers for people with dementia who wander, in addition to evaluating the effectiveness and acceptability of specific interventions to promote safe wandering.

There is a need to explore with all relevant stakeholders the boundaries between walking, safe wandering and unsafe wandering. Such in-depth qualitative research would help identify mutually agreed significant consequences/outcomes of wandering and provide better understanding of the different perspectives held by professional/lay carers and people with dementia, and may help facilitate a shift from the prevention of wandering to the promotion of safe walking.

Chapter 1

Introduction

Aim of the review

The aim was to provide a systematic review of the clinical effectiveness and cost-effectiveness of non-pharmacological interventions in the prevention of wandering in people with cognitive impairment/dementia and to assess the acceptability and ethical implications associated with their use. Qualitative methodology was also used to address acceptability and ethical issues.

Background

Description of the underlying problems

Wandering is a common characteristic of dementia, occurring in around 15–60% of those who are diagnosed with the illness,[1–4] with a diverse incidence found in both community-dwelling and institutionalised patients. It is often grouped together with other psychological and behavioural problems occurring in dementia.[5]

The term 'wandering' refers to a complex collection of different behaviours which occur for a multitude of reasons.[4] Initially, the global term 'wandering' was simply categorised into three components: wandering outside the home during the day, wandering outside at night and getting lost.[6] Wandering behaviour has been classified according to its geographical pattern: direct (i.e. straightforward movement to a destination), lapping (i.e. circuitous movement revising points sequentially along a path or track), pacing (i.e. back and forth movement between two points) or random (i.e. haphazard movement without repeating points in sequence).[7] In recognition of the complexity of wandering, a descriptive typology rather than a simple definition has been outlined.[4,8] The typology includes nine items: checking; pottering; aimless walking; walking with inappropriate purpose; walking with appropriate purpose but inappropriate frequency; excessive activity; night-time walking; attempts to leave home; and brought back home. In addition, the term 'sundowning' is widely used to describe people with dementia who become more confused and prone to wandering in the evening and during the night.[9] Another approach has been to study in depth the patterns and frequency of wandering and link these to discrete neurocognitive deficits.[10] Despite the term 'wandering' encompassing a complexity of behaviours, a single definition has been attempted, for example: 'a tendency to move about in either a seemingly aimless or disorientated fashion or in pursuit of an indefinable or unobtainable goal'.[11,12]

Hence it is generally acknowledged that the term wandering recognises a diverse spectrum of behaviours, which are often conflated with the term 'agitation' or 'agitated behaviour'.[13] Consequently, this may lead to difficulty in clearly defining the research question and outcome measures in studies.

Traditional responses to managing wandering

Wandering may be beneficial to people with dementia, providing a form of exercise, and improving circulation,[14] although the evidence is not strong.[15] In one very small observational study in a nursing home, pacing was found to be an indicator of good physical health.[15] However, it can be problematic to both the patient and carer, resulting in earlier institutionalisation,[16,17] physical harm, emotional distress and even death.[5,18]

Traditional responses to wandering include physical barriers (alarms, locks), physical restraints (Buxton chairs, tethers) and drugs (neuroleptic drugs). Neuroleptic drugs have harmful side-effects and the evidence reveals modest efficacy for their use in managing some behavioural problems in dementia.[19,20] Although such drugs maybe tolerated in the short term, longer term safety is a concern,[19] with one study showing that some may hasten cognitive decline and increase morbidity and mortality.[21] Also, a meta-analysis of controlled trials of neuroleptic drugs in dementia has revealed high placebo response rates.[22] Consequently, non-pharmacological interventions are currently recommended before the use of pharmacological methods.[20] In addition, the Committee on Safety of Medicines' recent recommendations that certain neuroleptic drugs (Risperidone and Olanzapine) should not be used for the treatment of behavioural problems in dementia[23] will further promote a non-

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pharmacological approach to the management of wandering.

Physical restraints may lead to physical consequences, such as pressure sores and infection, and psychological problems such as anxiety and distress and also physical violence.[24] From an ethical perspective, the use of physical restraints transgresses the principle of patient autonomy and leads to conflicting views over how best to do good (the principle of beneficence) while avoiding harm (the principle of non-maleficence).[25] In addition, moral concerns over the use of electronic means of surveillance, such as tagging, raise issues related to civil liberties.[26]

In view of the harmful consequences associated with pharmacological methods and the ethical and acceptability issues associated with the use of barrier/restraint methods to prevent wandering, a new perspective has evolved in the last decade with a shift from the prevention of wandering to the promotion of safe walking.[27–29] This new ethos attempts to balance the ethical dilemmas in recognising a person with dementia's need for autonomy and to be ambulatory whilst minimising their risk of harm. Such a change has resulted in a broader approach to management of wandering and a wide and diverse range of interventions to be considered in this review.

Descriptions of the interventions considered in this review

An ideal barrier to wandering would not limit other patient behaviour or lead to harm or distress in the patient and/or carer, would involve little carer training or involvement and would be relatively inexpensive.[30] More recent interventions aimed at meeting these objectives include:

- electronic devices that increase freedom and autonomy while minimising risk (such as electronic tagging and tracking devices)

- behavioural approaches (such as cognitive behavioural therapy, cognitive rehabilitation and reality orientation)
- multidisciplinary team and carer interventions (such as education and training of both formal and lay carers)
- prevention/distraction therapies (such as physical activity and planned walks, music therapy and occupational therapy)
- alternative therapies (such as homeopathy)
- sensory therapies (such as aromatherapy and a multi-sensory environment)
- environmental designs or modifications (such as signs, wandering pathways and gardens).

Subjective barriers, which are defined as visual modifications that the person with dementia may interpret as a barrier even if it is not physically so (e.g. painted bars on windows) were the subject of a recent Cochrane review, which found no suitable trials from which to conclude on their effectiveness.[31] A systematic review was therefore required to synthesise the evidence for the other non-pharmacological interventions listed above.

Questions assessed by the review

The following questions were considered:

- How effective and cost-effective are non-pharmacological interventions in the prevention of wandering in people with cognitive impairment/dementia in comparison to usual care?
- How acceptable are these interventions to people with cognitive impairment/dementia and their carers?
- What are the ethical implications of these interventions?

Chapter 2
Methods

This project combined a systematic review to determine the effectiveness, cost-effectiveness and acceptability and ethical implications of non-pharmacological interventions to prevent wandering in dementia and an exploratory qualitative study to explore acceptability/ethical issues in more depth.

Systematic review

The *a priori* methods used in the review are outlined in the research protocol (Appendix 1). This was sent to members of the advisory group for comments. It was also sent to a number of external experts in the field (see Acknowledgements), who were identified through project and advisory team meetings and selected on the basis of geographical coverage (UK, USA, Europe) and professional background (medicine, nursing, psychology). From their feedback, a number of changes were made to the protocol (Appendix 2).

Criteria for including studies in the review
Types of studies
Studies to evaluate effectiveness of interventions included: randomised controlled trials (RCTs), non-RCTs, controlled before-and-after studies, cohort studies (both prospective and retrospective) and case–control studies (both prospective and retrospective).

Studies to evaluate cost-effectiveness of interventions included those costing the intervention strategies or wandering behaviour and full economic evaluations assessing the intervention strategies.

Studies to evaluate acceptability/ethical issues included surveys of opinion, qualitative studies and discussion papers.

Studies could be published in any language.

Types of participants
The participants included in the review were people with acute or chronic cognitive impairment, of any age, who exhibited wandering behaviour[1,2,4,8] including people:

- with dementia, either unclassified or classified according to the major subtypes of vascular, Alzheimer's disease (AD), mixed (vascular and Alzheimer's) and Lewy Body, and also people who were chronically cognitively impaired but did not fulfil the accepted criteria for the classification of dementia (e.g. people with mild neuro-cognitive disorder)
- with a syndrome of acute cognitive impairment (delirium), whether or not there was evidence of pre-existing chronic cognitive impairment.

Studies were considered if diagnostic criteria such as Diagnostic and Standard Manual for mental disorders (DSM) IV or International Classification of psychiatric Diseases (ICD) 10 or equivalents were rigorously applied or, less adequately, where a description of patient assessment clearly indicates the presence of acquired cognitive impairment.[31]

Setting
Studies could take place in any care environment (e.g. home, hospital, other institution).

Types of intervention
The non-pharmacological interventions included one or a combination of the following:

- physical barriers (e.g. alarms, locks)
- physical restraints (e.g. ropes, tethers, Buxton chairs, cocoon)
- electronic/technological devices (e.g. electronic tagging and tracking devices, alarm pads to detect movement from bed, or other electronic means of monitoring)
- behavioural interventions (e.g. cognitive behavioural therapy, cognitive rehabilitation and reality orientation)
- multidisciplinary team interventions and/or carer interventions (education and training)
- prevention/distraction activities e.g. music therapy, physical activity, planned walking;
- alternative therapies (e.g. homeopathy)
- sensory therapies (e.g. aromatherapy, multi-sensory environment, massage/touch)

- environmental designs or modification (e.g. wandering areas, signs, pathways).

Studies were excluded if they assessed the following interventions (unless they formed part of the control group): pharmacological interventions to reduce wandering (e.g. neuroleptic drugs); subjective barriers (e.g. patterns on door or floor, mirrors, camouflage of door, concealment of view from window); combinations of interventions which included the above (e.g. where participants received a concomitant pharmacological intervention targeted at reducing wandering).

The control or comparator treatment could comprise:

- Usual care, that is, whatever criteria of care were in place before the intervention. This may involve a combination of methods (such as nurse/carer observation, medication, locked doors) and could be different in different studies.
- Sham therapy, which does not include the elements that the investigators believe to be effective in preventing wandering.

Types of outcome measures
Studies were included if they reported outcomes likely to be meaningful to those making decisions about interventions to prevent wandering in people with cognitive impairment. These included:

- Primary outcomes – any measure of wandering behaviour (e.g. number of wandering occurrences, number of attempted exits, number of successful exits, time until person found, distance wandered/unit time, time spent not wandering, wandering as measured by subscales of psychiatric behaviour scales).
- Secondary outcomes – number and nature of accidents; number and cause of deaths; withdrawal from treatment (as an indicator of tolerability); satisfaction with intervention to person and carers; quality of life of person and informal carers; anxiety/distress of person and informal carers; cost of care (supervision needed, burden of informal care, prescription of drugs, use of health and social services either as a direct result of wandering, e.g. falls, fractures, or side-effects of treatment); costs related to the technology adopted and its implementation (start-up costs and follow-up costs), including equipment, supervision, advice/training to carers, concomitant prescription of medication. Where possible,

outcome measures at the end of follow-up were abstracted.

Search strategy for identification of studies
The search strategy was refined by the study information specialist (FB) following advice from the advisory group and external experts. It included electronic database searches followed by handsearches in relevant literature sources such as reference lists from primary and review articles, journals, grey literature and conference proceedings and research registers. Full details of the search strategy can be found in Appendix 3.

Electronic searches
The following databases were searched for relevant primary studies: Cochrane Library (which includes CENTRAL, CDSR, DARE, HTA, NHS EED); MEDLINE; Current Contents – clinical medicine, social and behavioural sciences; EMBASE; Science Citation Index; Social Science Citation Index; CINAHL; PsycINFO; HEED; ADEAR (Alzheimer's disease clinical trials database); National Research Register; and Ageline (AARP database – USA); AgeInfo (Centre for Policy on Ageing – UK). A general web search included BIOME (health and life sciences gateway), Current Controlled Trials, ClinicalTrials.gov, Google and Zapmeta.

Grey literature
The following sources were searched to identify grey literature, such as dissertations, theses and conference proceedings: ISTP (ISI Science and Technology Proceedings); ZETOC (British Library database of conference proceedings) and Index to Theses.

Ethical issues
The following sources were additionally searched for papers on ethical issues: ETHX database and Bioethicsweb.

Additional literature searches
The reference lists from primary studies, systematic review articles (efficacy) and other review articles (ethics) identified through the electronic searches were also scanned to identify further studies for consideration. Handsearches of relevant journals not covered by the Cochrane Collaboration were carried out, and included the *Journal of Dementia Care* (1999 to 2004) and *Dementia* (2002 to 2004). Specialists in the field were also communicated to identify any further relevant unpublished data and grey literature. The list of studies that met the inclusion criteria was

sent to both internal and external subject experts to check the list for completeness.

Search terms

Searches were refined based on recommendations by members of the advisory and project teams. The search was not limited by language or publication status. Exact search strategies for different databases are listed in Appendix 3. The following sets of alternative terms were combined together, using relevant thesaurus headings and truncation as appropriate for each database.

Set 1: cognitive function
(a) Dementia, delirium, Alzheimer's, Pick, Huntington, Creutzfeldt, JCD, Binswanger, Korsakoff, Wernicke, Lewy

OR

(b) (cognition, memory) AND (impairment, decline, disorder, disturbance, defect, confusion).

Set 2: wandering behaviour
Wandering, walking, pacing, ambulation, escape, elopement, orientation, agitation, restlessness, sundowning.

Set 3: interventions
Tagging, tracking, alarms, electronic, restraints, locks, Buxton chairs, barriers, cocoons, complementary therapies, snoezelen, aromatherapy, sensory therapies, music therapies, exercise, environment, smart homes, lighting, design, education, management, therapy, behaviour, activities, distraction, prevention, intervention.

There was much discussion about the inclusion of the term 'agitation', which sometimes (but not always) includes 'wandering' as a subtype. Although this trebled the number of results, a review of the abstracts revealed a number of studies for potential inclusion in the review and it was therefore included.

Review strategy

Study selection

All abstracts (or titles if not available) were read independently by two reviewers (DH and LC) to discard irrelevant articles based on the agreed inclusion/exclusion criteria. Any disagreements were resolved by a third reviewer (LR). Full papers were obtained for all potentially relevant studies. A list of excluded articles was kept.
Independent review of the full articles was carried out by DH and LC, again with a third (LR) or fourth reviewer (JB) to resolve any uncertainties.

Ambiguous papers tended to be those which assessed the effect of interventions on agitated or 'problem behaviours', using a scale in which 'wandering' or 'pacing' was a subcategory, but where data specific to wandering was not reported. These included studies which used instruments such the NeuroPsychiatric Inventory (NPI),[32] which has a subscale of aberrant motor activity (specified as purposeless pacing), or INTERACT,[33] which has a specific subscale of wandering/restlessness. After discussion, it was decided to contact the authors of these studies and ask for the relevant raw data. Only studies which provided specific data on wandering behaviour and fulfilled all other criteria were included.

Studies using other instruments, such as the Cohen–Mansfield Agitation Inventory (CMAI),[34] which has a subscale of physically non-aggressive agitation, where it was not possible to separate data on wandering from other behaviours (e.g. disrobing), or such as the Gedragsobservatieschaal voor de Intramurale Psychogeriatric (GIP)[35] or the Organic Brain Syndrome scale (OBS),[36] where the behaviour being measured was unclear (e.g. restless behaviour), were also excluded.

Lists of both included and excluded studies were sent to the external experts to check for completeness and to identify any further unpublished data and grey literature.

With respect to the inclusion of studies in the review, database searching continued until 31 January 2005. However, the database search was ongoing until 31 March 2005, and any relevant studies identified between 1 February 2005 and 31 March 2005 were included in the section 'Availability of new information' (p. 44).

In some instances, additional information/data was required to determine either (i) whether the study could be included or excluded in the review or (ii) if already qualifying for inclusion, additional data were required for analysis. The relevant authors were contacted both by formal letter and email. For studies in group (i), authors were given until 28 February 2005 to respond. For studies in group (ii), the closure date for receipt of further information from authors of included studies was 31 March 2005. These dates were selected in order to allow authors sufficient time to respond yet still allow the project to be completed on time.

Studies included in the review

Figure 1 shows a flow chart of all the literature reviewed in this study. A list of studies included in
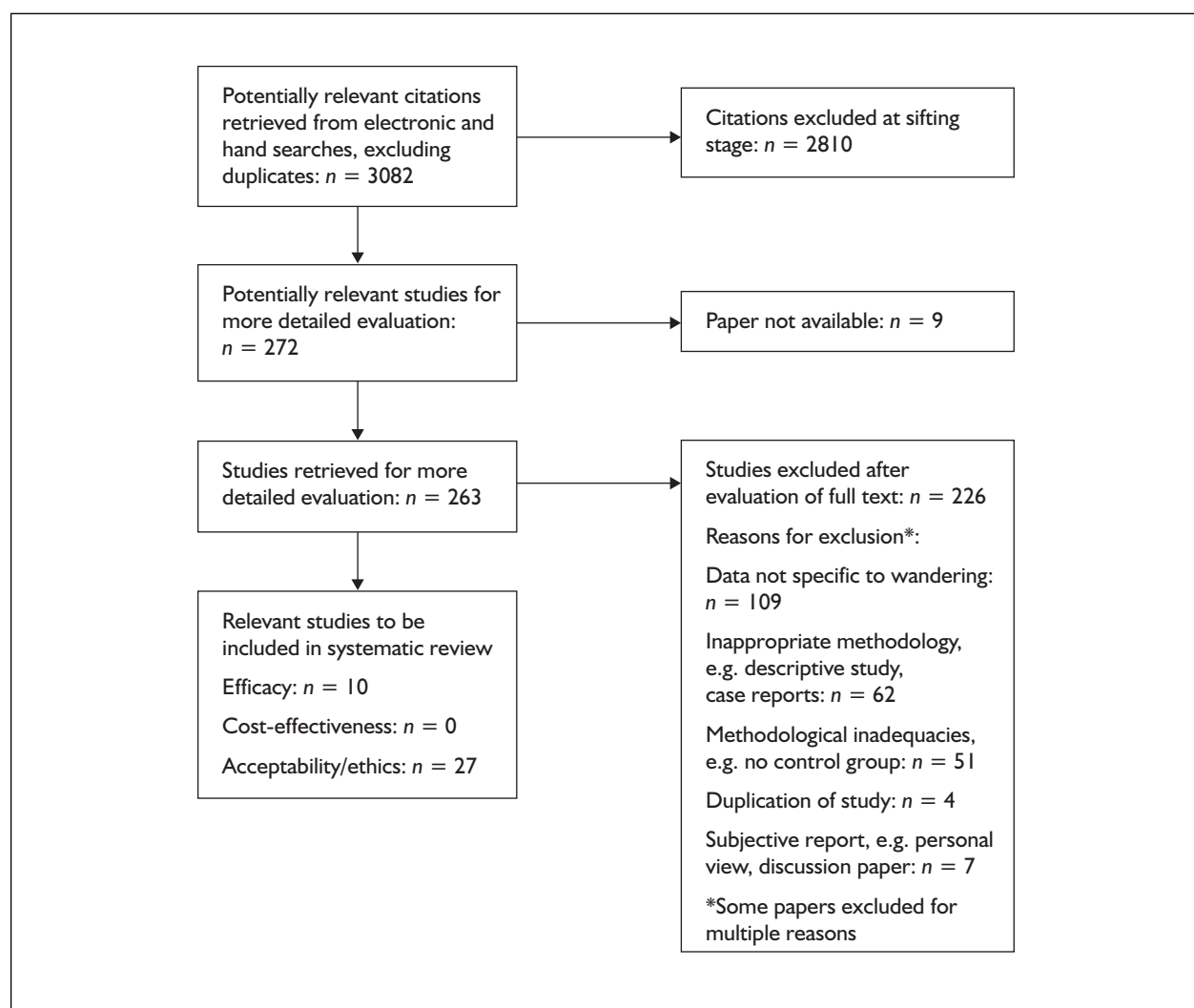
FIGURE 1 *Flow chart of all literature reviewed*

the review is provided in Appendix 4. A list of excluded studies and reasons for their exclusion was also maintained (Appendix 5). All identified literature was catalogued and tracked using Reference Manager bibliographic software.

Data extraction
Each study was independently assessed by two assessors, namely DH and one other reviewer with nominated responsibility: HD (efficacy), AV (health economics), TF (acceptability) and JH (ethical issues), to determine its methodological quality and to extract relevant data. A data extraction form was developed and piloted based on relevant checklists for quality assessment.[37,38] Additional information extracted included article type; year; country; study type; setting; sample details; type of intervention, its components, process and outcome measures (see Appendix 6).

Quality assessment
Efficacy studies
RCTs were assessed on adequacy of randomisation, concealment of allocation, blinding of outcome assessors and loss to follow-up.[39] In addition, information on individual or cluster randomisation and comparability of treatment groups at baseline was also recorded.

Non-RCTs were assessed on concealment of allocation, blinding of outcome assessors, comparability of treatment groups at baseline and adjustment for potential confounders.

Controlled before-and-after studies were assessed on blinding of outcome assessors, duration of data collection before and after intervention and changes introduced during the study period apart from the intervention.[40]

Observational studies were assessed on adjustment for potential confounders; susceptibility of design to selection bias; appropriateness of control population; reporting of missing data; percentage reduction in effective sample size due to missing data; appropriate statistical adjustment for reporting of several outcomes for each participant and completeness of ascertainment of outcome measures.[41]

The Guideline Recommendation and Evidence Grading (GREG) scheme[42] (see Chapter 3, *Box 1*) was used to summarise the quality of evidence and also of subsequent recommendations.

Acceptability and ethical issues

Acceptability of interventions was determined by assessing the evidence obtained within individual studies concerning acceptability/degree of satisfaction from both patients' and carers' perspectives and by considering the outcomes reported and the methods by which these were assessed. Qualitative studies were assessed on the range of perspectives included, appropriateness and replicability of methods, appropriateness and replicability of analysis, original evidence (including negative cases) reported and triangulation of findings.[37] Data extracted from individual studies was synthesised in a narrative review to address the following questions:

- Do patients and carers appear to find these interventions acceptable?
- Are some interventions viewed as more acceptable than others? (if so, which?)
- To what extent is the quality of evidence about the acceptability of these interventions adequate for informing decisions about the use of such interventions?

As few efficacy studies include a formal assessment of the ethical implications of interventions, additional papers relevant for the consideration of ethical arguments concerning wandering interventions were sought and included in the narrative. Reviewers extracted data indicating ethical issues, either by particular terms (e.g. dignity, rights) or ethical principles (e.g. beneficence, non-maleficence) or other expressions pointing towards value judgements.

Analysis of data

Analysis of efficacy data

As two out of the ten studies included in the efficacy review[43,44] used similar interventions (multi-sensory environment), designs and outcome measures, the results of these studies were pooled

in a meta-analysis using a fixed effect model and mean difference methods (see Chapter 3, *Figure 2*). A third study, which also evaluated multi-sensory environments,[45] was not included in the meta-analysis as no wandering was reported in either the treatment or control group.

Because the other interventions and the measures of wandering differed so much between studies, the results of the studies were not pooled in a formal meta-analysis. Nevertheless, the results of individual studies[46–50] which reported the standard deviations (SDs) of the effects of interventions are presented in a Forest plot (see Chapter 3, *Figure 3*), where the treatment effect in each study has been standardised by dividing by the overall standard deviation in the study.[51] Despite standardisation, the treatment effect may not be comparable between studies, as the underlying constructs measured may differ and the variance of the measures may be influenced by extraneous factors.

The results of studies which did not report SDs could not be presented graphically.[52,53]

Analysis of cost-effectiveness data

None of the studies retrieved investigated the cost-effectiveness of the intervention strategies, and no cost information about the interventions was reported in the studies included in the review (*Figure 1*). However, the studies provided some data on the resources utilised to deliver the intervention and the comparator. Further information was sought from the authors, which would have allowed the undertaking of a parallel costing exercise. However, no further data on either the resources used or the costs involved were received by 31 March 2005.

As part of the cost-effectiveness study, it was originally intended to develop an epidemiological model and associated costing model, nested within a Markov cycle tree (Appendix 1). However, this could not be achieved owing to the paucity and poor quality of the clinical, epidemiological and cost data retrieved (Appendix 2). A pragmatic decision was made, however, to utilise the acquired data to develop a framework for a possible Markov model which could be used in future studies. A description of the methods to develop the framework and details of the additional epidemiological literature and cost data required for the framework are presented in Appendix 7.

Analysis of ethical/acceptability data

The inclusion of qualitative data in a systematic review is a contested area and many systematic

reviews, especially Cochrane reviews, focus exclusively on efficacy studies. There is currently little consensus as to how these data should be approached and a variety of methods have been suggested.[54,55] This study used a narrative summary in order for the qualitative data to be interpreted and allowed systematic integration with the quantitative data analysis.[54]

The relevant papers were analysed as 'original transcripts' and coded thematically as such. Initially two papers were coded in detail by members of the project team (DH, TF, JH, LC, LR), who then met to discuss codes and develop the initial coding frame. This provided the opportunity to discuss any discrepancies in interpretation and ensured the development of an analysis strategy based on shared understanding across the project team. The coding frame was piloted on a further two papers and refined accordingly. The remaining papers were then coded following the agreed coding frame (see Appendix 8). Coded papers were imported into the Non-numeric Unstructured Data Index Searching and Theorising (NUD*IST) software program for the organisation and comparison of qualitative data. A cumulative comparative analysis was carried out to determine the main themes regardless of focus (ethics or acceptability) or intervention. Coding (and cross-coding) was compared across all of the papers, and categories were collapsed and merged, until three distinct but inter-related themes emerged. This was followed by a condition comparative analysis to examine any differences or commonalities within the main themes between the interventions.[56]

Qualitative study

As the initial screening search, performed in order to develop the review protocol, revealed a limited amount of information on relevant stakeholders' perspectives on non-pharmacological interventions to prevent wandering in dementia, an exploratory qualitative study, comprising discussion groups with stakeholders, was incorporated into the review to explore this area in greater depth.

Four discussion groups were held ($n = 19$); two with formal carers ($n = 10$), one with lay carers ($n = 3$) and one with people with dementia ($n = 6$). The discussion groups with carers used task group methodology.[57]

A task group provides a focus group forum that enables relevant stakeholders to contribute to discussion about services and policies that may affect them.[57] They are designed to provide the opportunity for stakeholders to engage in informed debate about a particular issue from their own perspectives, usually with the aim of arriving at a decision or recommendation after a process of deliberation.

Three task groups were carried out with carers and facilitated by DH, TF and LR. The groups included the following participants:

- healthcare professionals including a clinical psychologist, an old age psychiatrist, an occupational therapist and a social worker ($n = 4$)
- formal carers including residential and nursing home managers and inpatient ward managers (old age psychiatry services) ($n = 6$)
- informal carers with experience of relatives with dementia who wandered ($n = 3$).

The aim of the task groups was to ascertain relevant stakeholders' views on the initial results of the systematic review in terms of effectiveness and ethical/acceptability issues of the interventions. Groups were therefore presented with the findings of the review and asked to consider the following study questions:

1. How useful and acceptable are the different types of approaches?
2. What are the ethical problems of the different approaches?
3. What principles would you wish to see considered in the development of such approaches?
4. What outcomes are meaningful to people with dementia and their families?

The information presented in the task groups is shown in Appendix 9.

As outlined in the study protocol (Appendix 1), it was initially planned to hold one-to-one interviews with people with dementia, as focus groups were presumed to be an inappropriate method for this population. However, recruitment of people with dementia for one-to-one interviews proved difficult. An opportunity to hold a focus group with an established group of people with mild dementia ($n = 6$) arose and this was considered by the project team to be a feasible and acceptable alternative to use to harness the views of people with dementia themselves, in place of the interviews. However, because of the cognitive impairment of the participants, it was agreed that this group would be less structured and shorter in

duration than the task groups with carers. The group facilitated by LC therefore consisted of a general discussion of interventions to manage wandering, rather than presentation of effectiveness data and consideration of study questions which was the format used with the task groups.

The task groups and older person discussion groups were taped and transcribed in full. One transcript was coded in detail by DH and LR to develop an initial coding frame. Discrepancies in interpretation were discussed and the coding frame refined. Anonymised transcripts were imported into the NUD*IST qualitative software program for the organisation of data and application of the coding frame using a constant comparison approach. Analysis was conducted using the thematic framework approach,[58] which is both deductive (a 'top-down' approach informed by the aims of the research and the study questions) and inductive (a 'bottom-up' approach grounded in the responses of the participants).

Analysis of both sets of qualitative data, the ethics/acceptability literature from the systematic review and the discussion group transcripts followed a similar approach. All data were coded openly by more than one member of the team; the team then met to agree the coding frame which was applied to all papers/transcripts. However, in the focus group transcripts, the specific research questions from the study (see Appendix 1) were used as the framework from which the themes emerged.

Ethics and confidentiality

This study was approved by Newcastle and North Tyneside Local Research Ethics Committee (Ref. 2003/202) and registered with the appropriate Newcastle, North Tyneside and Northumberland Mental Health NHS Trust in accordance with Research Governance procedure.

Chapter 3

Clinical effectiveness and cost-effectiveness

This chapter presents the results from the systematic review of the clinical effectiveness and cost-effectiveness of the considered interventions.

Results of the systematic review of clinical effectiveness studies

Characteristics of included studies: summary

Ten studies, enrolling 492 participants, met the review inclusion criteria[43–50,52,53] (see *Table 1* and Appendix 3): seven RCTs (five of parallel design[43,44,46–48] and two of crossover design[45,52]) and three non-RCTs (two of parallel design[49,50] and one of crossover design[53]).

Demographic characteristics

Eight studies reported mean age and in these the overall mean age of study participants was 79 years (range 54–98).[43–50] Seven studies reported gender and in these 41% of participants were male.[44–50] Only three studies reported ethnicity and in these all the participants were reported as 'Caucasian'.[47,49,53] The median duration of follow-up was 6 weeks, ranging from 1 week[48] to 1 year.[45] In seven studies, all participants were nursing home residents.[45–50,53] Four studies were carried out in the UK,[44–46,52] three in the USA,[48,49,53] two in Europe[47,50] and one in both the UK and Europe.[43]

Quality of included studies

Reporting of studies was generally poor and so the quality of the conduct of the studies was uncertain. Concealment of allocation could be confirmed as adequate in only one of the ten studies (10%).[44] Six studies (60%) reported the number of participants assigned to treatment and control groups.[43,44,46,47,49,50] Where this was not reported, we assumed that randomisation resulted in approximately equal-sized groups.[45,48,52,53] Blinding of the outcome assessors was confirmed in only two studies (20%).[46,52] Treatment and control groups were confirmed as comparable at baseline, with regard to age, sex and cognitive impairment, in four studies (40%).[46,47,49,50] Among the seven RCTs, randomisation could be confirmed as adequate in only two (29%).[43,44]

Interventions

Studies compared a variety of interventions (multi-sensory environments,[43–45] music therapy,[48] essential oils,[46,52] special care units,[49,50] physical activity,[47] individualised behaviour management programmes[53]) with control interventions (tactile stimulation[45] or activity sessions,[43,44] reading therapy,[48] control oils,[46,52] traditional units,[49,50] or usual care[47]); in one study, the regime for the control group was not reported.[53] Contact between participants and the providers of therapies varied from three times per day[52] to two times per week.[43–45]

Outcomes

The outcomes used to measure wandering varied between studies: seven studies used behavioural scales which included measures of wandering or pacing.[43–47,50,53] One study developed a satisfaction scale to measure functional and behavioural difficulties including wandering;[52] one study measured both the length of time the patients remained near to the therapist and the distance they wandered per hour;[48] and in one study the outcome was the number of occurrences of wandering.[49] None of the studies used any of the secondary outcome measures pre-specified in the research protocol [i.e. accidents (number and nature), deaths, reassurance for relatives (satisfaction/acceptability measures), quality of life for patients and informal carers (quality of life measures, patient anxiety/distress), cost of care (supervision needed, burden of informal care, prescription of drugs, use of health and social services either as a direct result of wandering such as falls or fractures or side-effects of treatment)]. In addition, costs related to the technology adopted and its implementation (start-up costs and follow-up costs), including equipment, supervision, advice/training to carers and concomitant prescription of medication.

Baker and colleagues[43,44] and McNamara and Kempenaar[45] used INTERACT and INTERACT short,[33] which were developed to measure levels of engagement in people with dementia before, during and after multi-sensory stimulation (Snoezelen). INTERACT (22 items) and INTERACT short (12 items) use a five-point scale from 'not at all' to 'nearly all the time'. One item on the scale is 'wandering/restless' behaviour. The validity and reliability of this instrument are not known.

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TABLE 1 Summary of the evidence for the effectiveness data

Study	Treatment (T) Comparison (C)	1. Country of study 2. Setting 3. Patient characteristics	1. Study design 2. Blinding 3. Randomisation 4. Concealment 5. N 6. Loss to follow-up 7. Mean duration of follow-up	1. Baseline comparability (age, gender, cognitive impairment) 2. Age in years: mean (range) 3. % male 4. % white	Outcome measures T: Mean (SD), n C: Mean (SD), n	Comment
Multi-sensory environments (Snoezelen)						
Baker et al., 1998[44]	T: Snoezelen (multi-sensory environment) (8 × 30 minutes/month) C: One-to-one activity sessions (8 × 30 minutes/month)	1. UK 2. Day centre, hospital day wards 3. Patients living in the community with a carer and attending day centres at least 2 days a week, with vascular dementia (7), Alzheimer's-type dementia (32), mixed vascular and Alzheimer's-type dementia (10) early Alzheimer's dementia (1)	1a. Randomised 1b. Parallel 2. No 3. Adequate 4. Adequate 5. 50 6. 3/50 (6%) from Snoezelen group 7. 2 months	1. Not reported 2. 78 (? – ?)[a] 3. 50% 4. Not reported	INTERACT scores for wandering/restless Low scores → less wandering Mean scores after 8 sessions: T: 1.27 (0.38), 22 C: 1.51 (0.69), 25 Mean scores during 8 sessions: T: 1.23 (0.33), 22 C: 1.33 (0.59), 25	Authors contacted for scores at end of follow-up. No reply received at 31.3.05
Baker et al., 2003[43]	T: Multi-sensory stimulation (4 × 2 sessions/week) C: Activity sessions (4 × 2 sessions/week)	1. UK, The Netherlands, Sweden (Swedish data not included in final results) 2. Day hospital (UK), residents of psycho-geriatric ward (The Netherlands, Sweden) 3. Patients with vascular dementia, Alzheimer's-type dementia, or mixed dementia, not confined to bed, mild to moderate cognitive impairment (MMSE 0–17)	1a. Randomised 1b. Parallel 2. No 3. Adequate 4. Unclear 5. 136 6. 19/136 (14%) I: 10/65 (15%) C: 9/71 (13%) 7. 4 weeks	1. Not reported 2. 82 (? – ?) 3. Not reported 4. Not reported	INTERACT scores for wandering/restless Low scores → less wandering Mean scores after 8 sessions: T: 1.3 (0.6), 55 C: 1.5 (0.8), 62 Mean scores during 8 sessions: T: 1.3 (0.5), 55 C: 1.3 (0.5), 62	Authors contacted for scores at end of follow-up. No reply received at 31.3.05

TABLE I *Summary of the evidence for the effectiveness data (cont'd)*

Study	Treatment (T) Comparison (C)	1. Country of study 2. Setting 3. Patient characteristics	1. Study design 2. Blinding 3. Randomisation 4. Concealment 5. N 6. Loss to follow-up 7. Mean duration of follow-up	1. Baseline comparability (age, gender, cognitive impairment) 2. Age in years: mean (range) 3. % male 4. % white	Outcome measures T: Mean (SD), *n* C: Mean (SD), *n*	Comment
McNamara and Kempenaar, 2001[45]	T: Multi-sensory environment (2 × 30 minutes/week) C: Tactile stimulation (2 × 30 minutes/week)	1. UK 2. Nursing home 3. Residents in residential/nursing home with multi-infarct dementia (5), mixed MID/AD (3), Lewy Body dementia (1)	1a. Randomised 1b. Crossover 2. No 3. Unclear 4. Not reported 5. 12 6. 1/12 (8%) 7. 6 weeks	1. N/A 2. 89 (79–98) 3. 73% 4. Not reported	INTERACT scores for wandering/restlessness. Low scores → less wandering. T: 0.0 (0.0), ? C: 0.0 (0.0), ?	
Music therapy						
Groene et al., 1993[48]	T: 5 × 15 minute individual sessions of music (1 session/day) C: 5 × 15 minute individual sessions of reading (1 session/day)	1. USA 2. Nursing home 3. Residents with AD who exhibit wandering behaviour	1a. Randomised 1b. Parallel 2. Unclear 3. Unclear 4. Not reported 5. 30 6. Not reported 7. 7 days	1. Not reported 2. 77.5 (60–91) 3. 47% 4. Not reported	Sitting/proximity times during 5th session High scores → less wandering T: 798.53 (182.39), ? C: 648.13 (381.00), ? Wandering behaviour (mph) inside and outside 5th session Low scores → less wandering T: 0.11 (0.08), ? C: 0.04 (0.03), ?	Authors contacted for scores at end of follow up. No reply received at 31.3.05

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TABLE 1 Summary of the evidence for the effectiveness data (cont'd)

Study	Treatment (T) Comparison (C)	1. Country of study 2. Setting 3. Patient characteristics	1. Study design 2. Blinding 3. Randomisation 4. Concealment 5. N 6. Loss to follow-up 7. Mean duration of follow-up	1. Baseline comparability (age, gender, cognitive impairment) 2. Age in years: mean (range) 3. % male 4. % white	Outcome measures T: Mean (SD), n C: Mean (SD), n	Comment
Landi et al., 2004[47]	T: Moderate intensity exercise programme C: Usual care	1. Italy 2. Nursing home 3. Patients with cognitive impairment	1a. Randomised 1b. Parallel 2. Not reported 3. Unclear 4. Not reported 5. 30 6. Not reported 7. 4 weeks	1. Yes (gender and cognitive impairment) 2. 80.9 (? – ?) 3. 50% 4. 100%	Minimum data set instrument for nursing home (MDS-NH), actual outcome measure for wandering unclear Low scores → less wandering T: 18 (16.4), 15 C: 40 (16.4), 15 SDs were estimated assuming (i) statistical significance was $p = 0.001$, (ii) a t-test (rather than Mann–Whitney test) had been used to assess differences and (iii) outcome reported is a continuous rather than a count variable (see Appendix 9)	Authors contacted for scores. No reply received at 31.3.05

Special care units

Study	Treatment (T) Comparison (C)	1. Country of study 2. Setting 3. Patient characteristics	1. Study design 2. Blinding 3. Randomisation 4. Concealment 5. N 6. Loss to follow-up 7. Mean duration of follow-up	1. Baseline comparability 2. Age in years: mean (range) 3. % male 4. % white	Outcome measures	Comment
Frisoni et al., 1998[50]	T: Special care units C: Traditional nursing homes	1. Italy 2. Nursing homes 3. Ambulatory patients with degenerative or vascular dementia, with behavioural disturbance, resident in home for at least 3 months, MMSE score <16	1a. Non-randomised 1b. Parallel 2. No 3. No 4. No 5. 66 6. 0/66 (0%) 7. 3 months	1. Yes 2. 81 (59–97) 3. 24% 4. Not reported	Aberrant Motor Behaviour subscale of NPI Low scores → less wandering. Final values: T: –7.5(5.0), 31 C: –6.9(4.7), 35	

TABLE 1 Summary of the evidence for the effectiveness data (cont'd)

Study	Treatment (T) Comparison (C)	1. Country of study 2. Setting 3. Patient characteristics	1. Study design 2. Blinding 3. Randomisation 4. Concealment 5. N 6. Loss to follow-up 7. Mean duration of follow-up	1. Baseline comparability (age, gender, cognitive impairment) 2. Age in years: mean (range) 3. % male 4. % white	Outcome measures T: Mean (SD), n C: Mean (SD), n	Comment
Swanson et al., 1993[49]	T: Special care unit C: Traditional units	1. USA 2. Nursing home 3. Residents with AD	1a. Non-randomised 1b. Parallel 2. No 3. No 4. No 5. 63 6. 41 (65%) 7. 12 months (varied by participant)	1. Yes 2. 72.5 (54–93)[a] 3. 91%[a] 4. 100%[a] [a] Based on 22 participants assessed.	No. of occurrences of wandering. Low scores → less wandering. T: 4 (2.0), 13 C: 2 (1.4), 9 SDs estimated assuming a Poisson distribution (see Appendix 9)	Authors contacted for scores at end of follow up. No reply received at 31.3.05.
Aromatherapy with essential oils						
Ballard et al., 2002[46]	T: Aromatherapy with Melissa essential oil (lemon balm), applied to patients' faces and arms twice a day C: Placebo (sunflower oil) applied as above	1. UK 2. 8 NHS nursing homes for people with severe dementia 3. Patients with clinically significant agitation (including motor restlessness) and severe dementia (CDR stage 3)	1a. Cluster randomised 1b. Parallel 2. Yes 3. Adequate 4. Unclear 5. 72 6. 1/72 (1%) I: 1/36 (3%) C: 0/36 (0%) 7. 4 weeks	1. Yes 2. 78.5 (? – ?) 3. 40% 4. Not reported	Aberrant Motor Behaviour subscale of NPI Low scores → less wandering Final values: T: –2.2 (2.7), 35 C: –4.5 (4.3), 36 Change from baseline in median: T: –4.0 (?), 35 C: –0.3 (?), 36 Change in number of 5-minute epochs during a 6-hour period during which pacing occurred: T: –4.5 (15.3), 35 C: +9.0 (17.1), 36	Additional unpublished data provided by authors

TABLE 1 Summary of the evidence for the effectiveness data (cont'd)

Study	Treatment (T) Comparison (C)	1. Country of study 2. Setting 3. Patient characteristics	1. Study design 2. Blinding 3. Randomisation 4. Concealment 5. N 6. Loss to follow-up 7. Mean duration of follow-up	1. Baseline comparability (age, gender, cognitive impairment) 2. Age in years: mean (range) 3. % male 4. % white	Outcome measures T: Mean (SD), *n* C: Mean (SD), *n*	Comment
Mitchell, 1993[52]	T: Essential oils, applied to skin or immediate environment 3 times/day C: Control oils, applied to skin or immediate environment 3 times/day	1. UK 2. Residential and day-care unit 3. Adults with dementia	1a. Randomised 1b. Crossover 2. Yes 3. Unclear 4. Not reported 5. 12 6. Not reported 7. 2 weeks	1. N/A 2. ? (64–91) 3. Not reported 4. Not reported	Satisfaction rating for wandering Low scores → less wandering T: 2.2 (?), ? C: 2.2 (?), ?	Authors contacted for scores at end of follow-up No reply received at 31.3.05
Individualised behaviour management						
Ingersoll-Dayton *et al.*, 1999[53]	T: Individualised behaviour management programmes C: Not reported	1. USA 2. Nursing home 3. Residents with dementia who display one or more of physical aggression, verbal aggression and/or wandering and visited by a family member every 2–3 weeks	1a. Non-randomised 1b. Crossover 2. Not reported 3. No 4. No 5. 21 6. Not reported 7. 7 weeks	1. N/A 2. ? (60–?) 3. Not reported 4. 100%	Caretaker Obstreperous Behavior Rating Assessment Scale (measures wandering and other dementia-related behaviours) Low scores → less wandering Frequency: T: 1.65 (0.14°), ? C: 1.38 (0.14°), ? Severity : T: 1.04 (0.22°), ? C: 0.72 (0.22°), ?	Authors contacted for missing data No reply received at 31.3.05

TABLE 1 Summary of the evidence for the effectiveness data (cont'd)

Study	Treatment (T) Comparison (C)	1. Country of study 2. Setting 3. Patient characteristics	1. Study design 2. Blinding 3. Randomisation 4. Concealment 5. N 6. Loss to follow-up 7. Mean duration of follow-up	1. Baseline comparability (age, gender, cognitive impairment) 2. Age in years: mean (range) 3. % male 4. % white	Outcome measures **T: Mean (SD),** *n* **C: Mean (SD),** *n*	Comment
					Mastery (caregiver's ability to handle resident's problem behaviours): T: 1.14 (0.2[a]), ? C: 0.60 (0.2[a]), ? [a] The SDs were estimated from *F*-statistics and are lower bounds as the estimation could not allow for the repeated measures nature of the ANOVA presented in the trial report (see Appendix 9)	

ANOVA, analysis of variance; CDR, Clinical Dementia Rating scale; MDS-NH, Minimum Data Set instrument for Nursing Homes; MID, multi-infarct dementia; MMSE, Mini Mental Health Examination; NA, not applicable; NPI, NeuroPsychiatric Inventory.
[a] ?, unknown data that was not reported in the paper and could not be acquired from the original authors.

Ballard and colleagues[46] and Frisoni and colleagues[50] used the NPI,[32] which assesses ten behavioural disturbances occurring in dementia patients including aberrant motor activity (defined as purposeless pacing). Each behaviour is rated by combining the score for severity (using a three-point scale from mild to severe) with the score for frequency (using a four-point scale from less than once per week to once or more per day). The NPI has been reported to have good content validity, inter-rater and test–retest reliability.[32]

Ingersoll-Dayton and colleagues[53] used a modified version of the Caretaker Obstreperous Behavior Rating Assessment (COBRA) Scale.[59] This collects information about the frequency and severity of 30 problem behaviours associated with dementia, including wandering. It was modified by adding an item measuring mastery of problem behaviours as proposed by Lawton and colleagues.[60] The scales for frequency, severity and mastery range from zero to four with lower scores indicating that the behaviour occurred infrequently, was not severe and was easily mastered. Measurement of wandering behaviour included the items pacing, wandering and hyperkinesia. The motor abnormalities subscale of the COBRA has been reported to have good test–retest and inter-rater reliability.[59]

Landi and colleagues[47] used the Minimum Data Set instrument for Nursing Homes (MDS-NH), which collects data on the functional status of nursing home residents. It includes items about behaviour problems including wandering. The MDS-NH is reported to have adequate reliability and clinical validity.[61]

Mitchell[52] developed his own satisfaction scale, choosing six criteria to measure functional and behavioural difficulties, including wandering, which were rated from 0 to 3 (very poor, poor or satisfactory). No assessment of the validity or reliability of the scale was reported.

Groene[48] used seating/proximity times and speed of wandering as outcome measures. Seating/proximity behaviour was defined as 'the amount of time a participant was actually either seated or in the session room during the 15-minute session'. This was recorded by video-taping and counting the amount of time in seconds. Reliability of this measure was by independent verification of over 20% of the video-taped examples. Wandering behaviour was measured in miles per hour by the use of pedometers or a wheelchair measuring device.

Swanson and colleagues[49] developed an Individual Incident Record (IIR) to record occurrences of a number of events, including wandering behaviour. Inter-rater agreement of two independent staff recordings was assessed for one shift for five randomly chosen residents for each of the 12 two-month data collections, and agreement was reported to range from 85 to 97% throughout the study.

Characteristics of included studies: details

Multi-sensory environments (Snoezelen)
Baker and colleagues, 1998[44]
This was an RCT of parallel design, comparing Snoezelen (described as multi-sensory stimulation using unpatterned, non-sequential visual and auditory stimuli, a non-directive, enabling approach by keyworkers and requiring no intellectual or physical demands from patients) with a control intervention of one-to-one activity (described as non-multi-sensory, using patterned, often sequential stimuli, a directive approach from keyworkers and requiring intellectual or physical demands from patients). It was conducted in a day centre and hospital day wards in the UK. Fifty patients with dementia living in the community with a carer and attending day centres at least 2 days per week were eligible for inclusion. Included patients had vascular dementia (7), Alzheimer's-type dementia (32), mixed vascular and Alzheimer's-type dementia (10) and early Alzheimer's-type dementia (1). Their mean age was 78 years and 50% were male. Ethnicity was not reported.

Both randomisation and concealment of allocation were confirmed as adequate; outcome assessors were not blinded to the treatment group of participants. Participants were followed up for 2 months and loss to follow-up was 3/50 (6%), all from the Snoezelen group.

Both experimental and control groups received eight 30-minute sessions per month. Outcome measures included INTERACT scores[33] comparing wandering/restlessness in the Snoezelen and control groups. The mean scores in both groups (i) after the sessions and (ii) during the sessions were reported, averaged over all treatment sessions. Mean scores both during and after the eight sessions showed a small, statistically non-significant benefit of the Snoezelen treatment compared with control. As scores at the end of follow-up were not reported, we were unable to evaluate the final differences between groups at the end of the study. We wrote to the authors to request these scores, but did not receive a reply.

This study did not provide evidence that a multi-sensory environment (Snoezelen) effectively prevents/reduces wandering.

Baker and colleagues, 2003[43]
This was an RCT of parallel design, comparing multi-sensory stimulation (described above) with a control activity such as playing cards, looking at photographs or doing quizzes. It was conducted simultaneously at three centres in the UK (in day hospitals) and in The Netherlands and Sweden (in psycho-geriatric wards). A total of 136 patients (94 from the UK, 26 from The Netherlands, 16 from Sweden) with AD, vascular dementia or mixed dementia, not confined to bed and with moderate to severe cognitive impairment [Mini Mental State Examination (MMSE)[62] scores 0–17] were eligible for inclusion. Included patients had a mean age of 82 years. Gender and ethnicity were not reported.

Randomisation was confirmed as adequate but concealment of allocation was unclear; outcome assessors were not blinded to the treatment group of participants. Participants were followed up for 4 weeks and loss to follow-up was 10/65 (15%) in the treatment group and 9/71 (13%) in the control group.

Both experimental and control groups received eight 30-minute sessions twice per week. Outcome measures included INTERACT[33] scores comparing wandering/restlessness in the two groups. Owing to low numbers in the activity group in Sweden, the mean scores during and after the sessions (averaged over all sessions) in treatment and control groups were reported for the UK and The Netherlands only. Mean scores after sessions showed a small, statistically non-significant benefit of the multi-sensory treatment compared with control; mean scores during the sessions showed no difference between the treatments. As scores at the end of follow-up were not reported, we were unable to evaluate the final differences between groups at the end of the study. We wrote to the authors to request these scores, but did not receive a reply.

This study did not provide evidence that a multi-sensory environment (Snoezelen) effectively prevents/reduces wandering.

McNamara and Kempenaar, 2001[45]
This was an RCT of cross-over design, comparing multi-sensory stimulation (using visual equipment, music and hand massage) with tactile stimulation (hand massage only). It was conducted in a nursing/residential home in the UK. Twelve residents with multi-infarct dementia (MID), AD, mixed MID–AD or Lewy-Body dementia over the age of 65 years were eligible for inclusion. Participants' mean age was 89 years and 73% were male. Ethnicity was not reported.

Neither randomisation nor concealment of allocation was confirmed as adequate; outcome assessors were not blinded to the treatment group of participants. Participants were followed up at the end of each study period of 6 weeks and loss to follow-up was 1/12 (8%).

Both treatment and control groups received two 30-minute sessions per week. Outcome measures included INTERACT scores[33] comparing wandering/restlessness in both groups. The mean scores in both groups (i) during the sessions and (ii) after the sessions were presented, averaged over all sessions.

This study reported no wandering in any of the participants at the end of follow-up and so the study yielded no information about the effectiveness of multi-sensory stimulation.

Music therapy
Groene, 1993[48]
This was an RCT study of parallel design, comparing music attention (described as listening to music, playing percussion instruments, singing, movement or dance) with reading attention (described as reading aloud to or by the participant). It was conducted in a special Alzheimer's unit in a nursing home in the USA. Thirty residents with AD and exhibiting wandering behaviour (defined as the ability to walk or move by wheelchair without assistance) were eligible for inclusion. Included residents had a mean age of 77 years and 47% were male. Ethnicity was not reported.

Neither randomisation nor concealment of allocation could be confirmed as adequate; blinding of outcome assessors was also unclear. Each participant was followed up for 7 days. Loss to follow-up was not reported.

Both groups received seven 15-minute sessions, but after the fifth session the music and reading interventions were interchanged. Therefore, we abstracted the outcome measures at the end of the fifth session. Outcome measures were sitting/proximity times and speed of wandering (in miles per hour) during the sessions.

The study indicated that people in the reading therapy (control) group were significantly less likely to wander than those in the music therapy group based on one measure of wandering (speed of wandering) but more likely to wander based on the other measure (sitting/proximity times).

Exercise
Landi and colleagues 2004[47]

This was an RCT of parallel design, comparing a moderate intensity exercise programme (described as a combination of aerobic/endurance activities, strength training, balance and flexibility training) with usual care. It was conducted in an Alzheimer's unit of a nursing home in Italy. Thirty patients with mild cognitive impairment were eligible for inclusion. Included patients had a mean age of 81 years, 50% were male and all were reported as 'Caucasian'.

Neither randomisation nor concealment of allocation could be confirmed as adequate; blinding of outcome assessors was not reported. Participants were followed up for 4 weeks. Loss to follow-up was not reported.

The number and length of sessions were not reported. Outcomes were measured using the MDS-NH;[61] however, the actual outcome measure of wandering presented for both groups is unclear.

The study found a significant reduction in wandering among participants in the exercise group. However, SDs of the outcome were not reported. Despite attempts to contact the authors for additional relevant data, no such data were forthcoming. Therefore we estimated confidence intervals on the reduction in wandering (see *Figure 3*) assuming (i) statistical significance was $p = 0.001$, (ii) a t-test (rather than Mann–Whitney test) had been used to assess differences and (iii) the outcome reported was a continuous rather than a count variable. If the level of statistical significance were assumed to be $p = 0.05$, the confidence interval (CI) on the estimated reduction in wandering in the treatment group compared with the control group would be wider than that shown in *Figure 3*. Full details of the estimation of SDs of measures of wandering are provided in Appendix 9.

This study provided some evidence that moderate intensity exercise may reduce wandering.

Special care units
Frisoni and colleagues 1998[50]

This was a non-RCT of parallel design, comparing special care units (no description

provided) with traditional nursing homes in Italy. Sixty-six patients with degenerative or vascular dementia, with behavioural disturbance, residing for at least 3 months, not confined to bed and with an MMSE score of <16 were eligible for inclusion. Included patients had a mean age of 81 years and 24% were male. Ethnicity was not reported.

Although the study was not randomised, the intervention and control groups were similar at baseline in terms of age, gender and cognitive impairment.

Outcome assessors were not blinded to the treatment groups of participants. Participants were followed up for 3 months; loss to follow-up was not reported.

Outcome measures included NPI-1232 scores comparing aberrant motor behaviour in the treatment and control groups. The mean scores in both groups after 3 months were reported.

No significant difference in pacing behaviour between the groups was found after 3 months.

This study did not provide evidence that the special care unit effectively prevents/reduces wandering.

Swanson and colleagues, 1993[49]

This was a non-RCT of parallel design, comparing a special care unit (reduced stimuli environment and programming) with a traditional unit. It was conducted in a state-owned long-term care facility in the USA. Sixty-three ambulatory residents with irreversible dementia were eligible for inclusion. Twenty-two participants were assessed at the end of follow-up; these participants had a mean age of 72 years, 91% were male and all were reported as 'Caucasian'.

Although the study was not randomised, the intervention and control groups were similar at baseline in terms of age, gender and cognitive impairment.

Outcome assessors were not blinded to the treatment groups of participants. Participants were followed up for up to 12 months and loss to follow-up was high: 41/63 (65%).

The study reported the number of occurrences of wandering, but did not report the number of individuals who wandered; failure to allow for clustering of occurrences of wandering within

individuals resulted in CIs on the estimated effect of treatment being artefactually narrow. This study found that patients in traditional units were less likely to wander than those in special care units, based on the number of occurrences of wandering. Although the effect appears statistically significant, allowance for clustering of occurrences of wandering within individuals would widen the CI on the estimated effect and therefore there may actually be no statistically significant difference between treatment and control groups. The authors suggested that the lower risk of wandering among participants in the traditional unit may have been because patients at high risk of wandering were assigned to the special care unit.

Full details of the estimation of standard deviation of measures of wandering are provided in Appendix 9.

This study did not provide evidence that the special care unit effectively prevents/reduces wandering.

Aromatherapy with essential oils
Ballard and colleagues 2002[46]
This was a cluster RCT of parallel design, comparing aromatherapy using the essential oil *Melissa officinalis* (lemon balm) with a placebo oil (sunflower oil). It was conducted in eight NHS nursing homes in the UK and nursing homes rather than individuals were randomised to receive treatment or control interventions. Seventy-two patients with severe dementia [Clinical Dementia Rating (CDR)[63] scale, Stage 3) and clinically significant agitation (defined as a cluster of symptoms including anxiety, irritability, motor restlessness and abnormal vocalisation) were eligible for inclusion. Included participants had a mean age of 78 years and 40% were male. Ethnicity was not reported.

Randomisation was confirmed as adequate but concealment of allocation was unclear; outcome assessors were blinded to the treatment group of participants. Participants were followed up for 4 weeks and loss to follow-up was 1/72 (1%), due to one person dropping out of the treatment group.

Both treatment and control groups received application of oils to the face and arms twice per day. Outcome measures included NPI scores[32] comparing aberrant motor behaviour (pacing) in the treatment and control groups. The change in median score in both groups was reported. Further data on the mean in treatment and control groups of (i) aberrant motor behaviour at end-point and

(ii) the number of 5-minute periods during which each individual was pacing were received directly from the authors (Ballard C. Kings College, London; personal communication, 2005).

The study showed a reduction in pacing in the active treatment group compared with the control group on all three outcome measures. Although the reduction in median aberrant motor behaviour was reported to be statistically significant, no allowance was made in statistical analysis for randomisation at the level of nursing home rather than individual, and it is unclear whether this reduction would have remained statistically significant if the differences between treatment and control had been analysed correctly, allowing for this clustering of individuals within nursing homes.

We analysed the mean aberrant motor behaviour at end-point, making an approximate allowance for clustering of individuals within nursing homes.[64] Based on the average cluster size, and assuming an intra-cluster correlation coefficient of 0.10, the effective sample size was estimated to be 20 patients in both treatment and control groups. Assuming this effective sample size, the reduction in aberrant motor behaviour in the treatment group compared with the control group was of marginal statistical significance ($p = 0.05$).

This study showed some reduction in wandering behaviour for people receiving essential oils, but the finding was of marginal statistical significance.

Mitchell, 1993[52]
This was an RCT of crossover design, comparing aromatherapy using essential oils (lemon balm and lavender) with neutral control oil (grapeseed oil). It was conducted in a residential and day-care unit in the UK. Twelve subjects with dementia were eligible for inclusion. Included participants were aged between 64 and 91 years. Gender and ethnicity were not reported.

Neither randomisation nor concealment of allocation could be confirmed as adequate. Outcome assessors were blinded to the treatment group of participants. Participants were followed up for 2 weeks. Loss to follow-up was not reported.

Both treatment and control groups received application of oils to the skin and immediate environment three times per day. Outcome measures included staff or carers' ratings of satisfaction with wandering behaviour (purposeless roaming) in both groups. The mean weekly ratings

in both groups were presented. The SD of the effect of treatment was not reported, so we were unable to estimate the 95% CIs on the treatment effect or the weight which should be ascribed to this study.

No effect of essential oils on wandering compared to control oils was found.

Individualised behaviour management
Ingersoll-Dayton and colleagues 1999[53]

This was a non-RCT of crossover design, evaluating individualised behaviour management programmes (using a solution-focused approach based on knowledge of the resident). The type of care given to the control group was not reported. The crossover design may not have been the optimum design as carers may have continued to use strategies recommended in the first treatment period during the second treatment period.

The study was conducted in two nursing home facilities in the USA. Twenty-one residents with dementia, aged 60 years or over, who displayed one or more of physical aggression, verbal aggression or wandering and who were visited by a family member every 2–3 weeks were eligible for inclusion. Included residents were all reported as 'Caucasian'. Age and ethnicity were not reported.

Blinding of outcome assessors to the treatment group of participants was not reported. Participants were followed up for 7 weeks. Loss to follow-up was not reported.

Outcome measures included COBRA scale[59] scores comparing frequency, severity and mastery over wandering behaviours in the two groups. Mean scores were reported for both groups, averaged over three time points during the study. The SD of the effect of treatment was not reported, but was estimated from *F*-statistics, which were reported.

However, as this estimation could not allow for the repeated measures nature of the analysis of variance presented in the trial report, the estimated SDs are lower bounds to the actual SDs.

As the study did not report scores at the end of follow-up, we were unable to evaluate the final differences between groups at the end of the study. Based on the averages over the three time points during the study, patients in the control group were less likely to wander than those receiving individualised behaviour management programmes, but it was unclear whether this effect was statistically significant.

Full details of the estimation of standard deviation of measures of wandering are provided in Appendix 9.

This study did not provide evidence that the individualised behaviour management programme was effective in preventing/reducing wandering.

Evidence synthesis
Multi-sensory environments
As the studies of Baker and colleagues[43,44] of multi-sensory environments used similar interventions, designs and outcome measures, the results of these studies were pooled in a meta-analysis using a fixed effect model and mean difference methods (*Figure 2*).

Overall, the pooled effect of multi-sensory environment on wandering/restlessness during sessions was a statistically non-significant reduction of 0.03 (95% CI –0.12 to 0.18) in the INTERACT score; the pooled effect of treatment on walking/restlessness after sessions was a statistically significant reduction of 0.22 (95% CI 0.02 to 0.41). However, the observation period was limited to 10 minutes post-intervention.

Music therapy, exercise, aromatherapy and special care units
The results of individual studies[46–50] which reported the SDs of the effects of interventions are presented in a Forest plot (*Figure 3*), where the treatment effect in each study has been standardised by dividing by the overall standard deviation in the study.[51]

The Forest plot summarises:

- the conflicting findings of the two different outcomes used in the study of music therapy[48]
- the statistically significant effect of exercise in reducing wandering[47]
- the lack of consistent robust evidence for the effectiveness of special care units in reducing wandering[49,50]
- the statistically significant effect of aromatherapy, based on one study[46] (the other study which evaluated aromatherapy did not report the standard deviation of the effect of treatment[52]).

Individualised behaviour management
The study of individualised behaviour management did not report the SD of the effect of treatment and our estimated SDs were lower bounds to the actual SDs. We were therefore unable to present graphically the results of this study.[49]
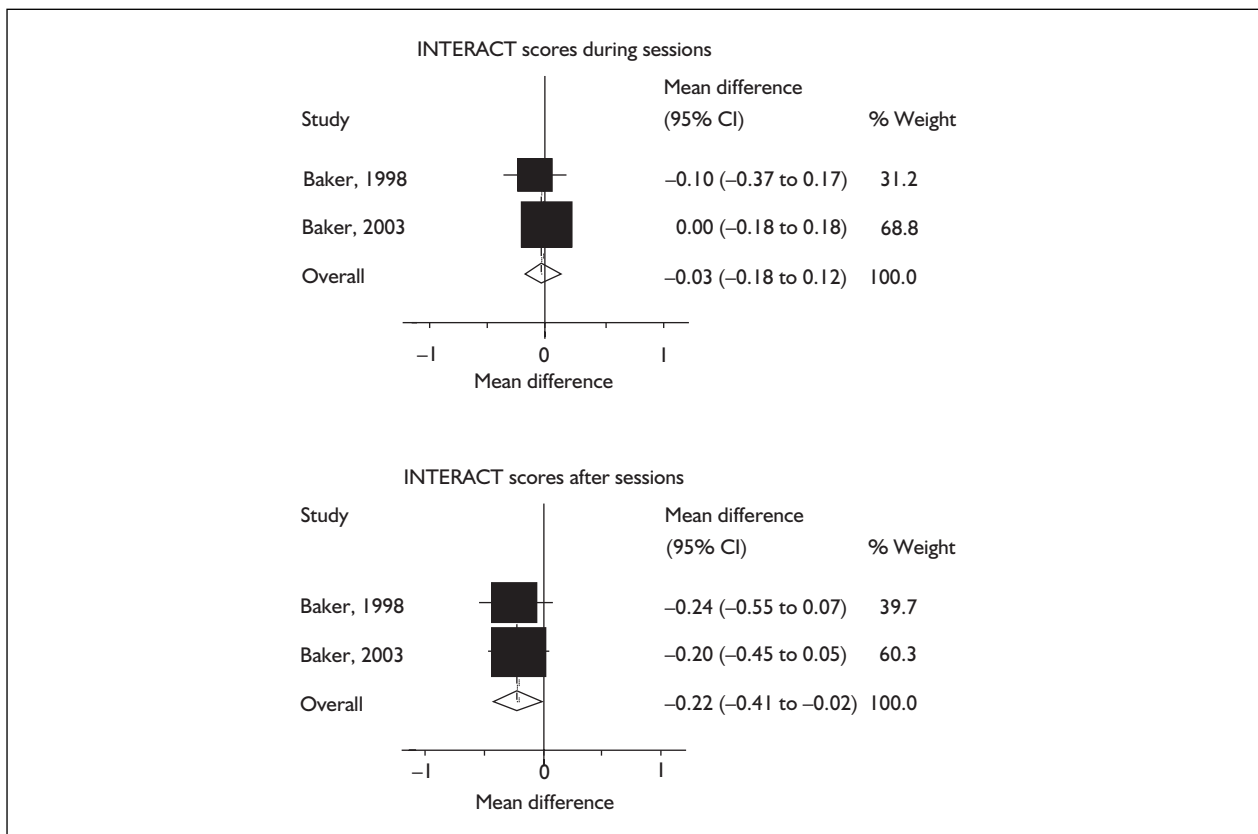
FIGURE 2 *Meta-analysis of studies of multi-sensory environments*[43,44]

Grading of evidence for each type of intervention

Within each area of intervention, evidence was assigned a grade using the GREG scheme[42] (*Box 1*) through discussion (DH, HD, LR). The quality of studies of each type of intervention is summarised and evidence grade assessments presented in *Table 2*; the evidence was deemed to be of poor quality for all areas of intervention.

Summary of clinical effectiveness results
Multi-sensory environment
Three RCTs enrolling 198 participants were included in the review.[43–45] One of the studies was very small (12 participants) and short term and yielded no information about the effectiveness of multi-sensory environments in reducing wandering.[45] Neither of the other two studies[43,44] separately showed multi-sensory environments to be effective, but when the results were pooled there was a small but statistically significant reduction in restlessness immediately after therapy sessions. However, the practical importance of such a small change is doubtful; further wandering

was not measured at the end of follow-up, so it is unclear whether there was a cumulative long-term effect. Further, the follow-up period in these studies was short (4 and 8 weeks).

We found no robust evidence for the effectiveness of multi-sensory environment; the evidence identified was of low quality.

Music therapy
The one RCT, enrolling 30 participants, which compared music therapy with reading therapy as a control intervention provided no evidence that music therapy reduced wandering. The group receiving music therapy showed a non-significant reduction in wandering on one measure (sitting/proximity times), but the control group receiving reading therapy showed a significant reduction in wandering on another measure (speed of wandering).

We found no evidence for the effectiveness of music therapy; the identified evidence was of low quality.
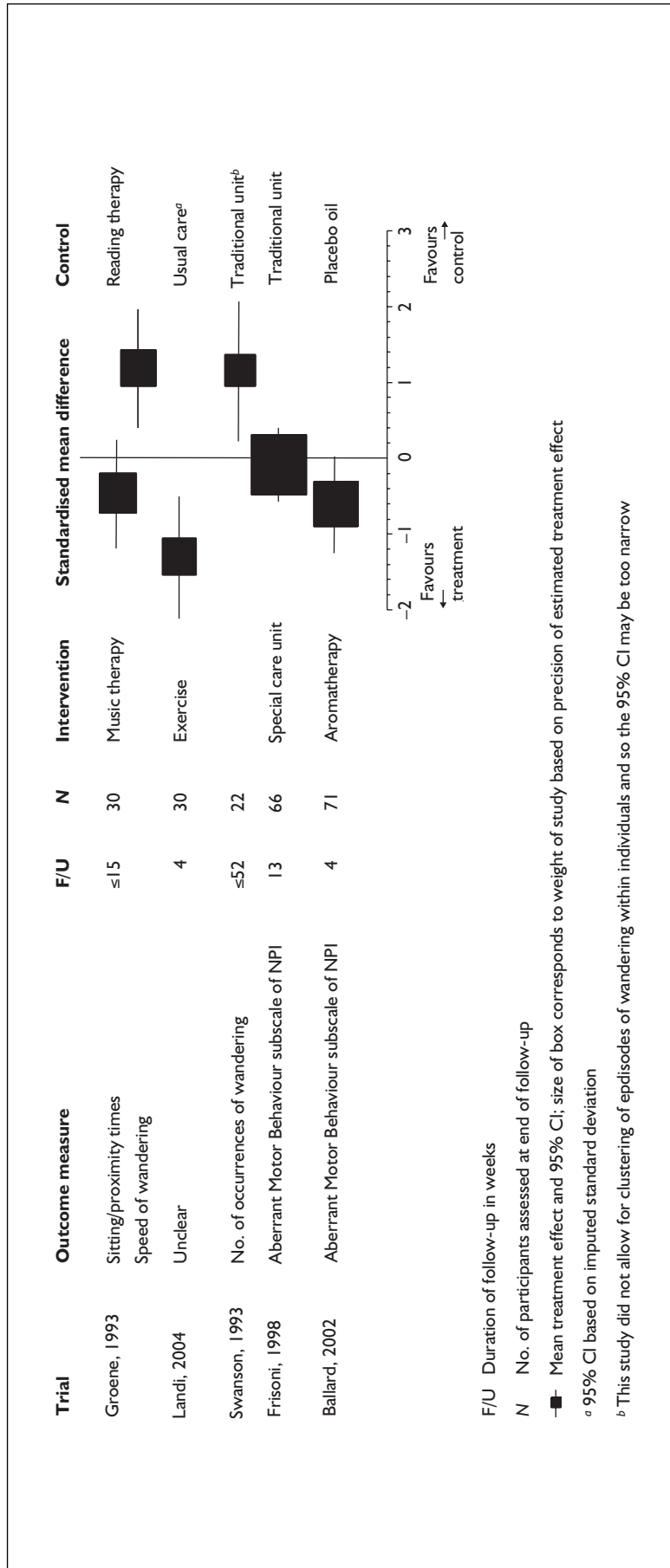
23

Trial	Outcome measure	F/U	N	Intervention	Standardised mean difference	Control
Groene, 1993	Sitting/proximity times Speed of wandering	≤15	30	Music therapy		Reading therapy
Landi, 2004	Unclear	4	30	Exercise		Usual care[a]
Swanson, 1993	No. of occurrences of wandering	≤52	22			Traditional unit[b]
Frisoni, 1998	Aberrant Motor Behaviour subscale of NPI	13	66	Special care unit		Traditional unit
Ballard, 2002	Aberrant Motor Behaviour subscale of NPI	4	71	Aromatherapy		Placebo oil

F/U Duration of follow-up in weeks

N   No. of participants assessed at end of follow-up

■   Mean treatment effect and 95% CI; size of box corresponds to weight of study based on precision of estimated treatment effect

[a] 95% CI based on imputed standard deviation

[b] This study did not allow for clustering of epdisodes of wandering within individuals and so the 95% CI may be too narrow

FIGURE 3 *Forest plot of individual studies which reported standard deviations of the intervention effects*

BOX I *GREG scheme for assessing evidence and writing recommendations[42]*

EVIDENCE

Evidence statements provide information about disease, diagnosis and treatment, and are used to support recommendations. Each evidence statement is graded by scoring the study design and applying quality corrections.

Design		**Notes**
Design scores		i. Blinding refers to independent interpretation of a test and reference standard.
Treatment		ii. An incident cohort is identified and followed in time from a defined point in the progress of disease or care.
Randomised controlled trial	1	iii. Important flaws may be judged to occur when adequate standards of research are not followed or are unreported in published findings. Potential examples include failure to analyse by intention-to-treat, over-interpretation of secondary analyses and failure to adjust for potential confounding in non-randomised designs. For diagnostic studies this includes the need for an adequate reference standard and to apply different tests in an adequately short time-scale.
Non-randomised controlled study	2	
Uncontrolled study	3	
Diagnosis		
Blinded cohort study[i]	1	
Unblinded cohort study	2	
Other design	3	
Prognosis		
Incident cohort study[ii]	1	
Other cohort study	2	iv. Sparse data (too few events or patients) are the most common reason for imprecision. A confidence interval including both no effect and a clinically important effect is an example of an imprecise finding.
Descriptive data		
Population data	1	
Representative sample	2	v. Consistency in (1) design (involves methods, patients, outcome measures) and (2) findings (involves homogeneity of summary estimates). Independence refers to the availability of research from at least two independent sources. Evidence of publication bias also denotes lack of consistency.
Convenience sample	3	
Quality corrections		
Flawed design, conduct or analysis[iii]	+1	
Imprecise findings[iv]	+1	
Lack of consistency or independence[v]	+1	vi. Adequate relevance requires (1) use in studies of a relevant patient-oriented health outcome or a strongly linked surrogate end-point and (2) a sufficiently representative and relevant patient group or mix.
Inadequate relevance[vi]	+1	
Very strong association[vii]	-1	
Evidence grade	Score	
• I: High	≤ 1	vii. In comparative designs a very strong association can raise the quality score.
• II: Intermediate	2	
• III: Low	≥ 3	

RECOMMENDATIONS

Recommendations provide guidance about appropriate care. Ideally, these should be based on clear evidence: a robust understanding of the benefits, tolerability, harms and costs of alternative patterns of care. They also need to be feasible in the healthcare setting addressed. There are three unique categories, and each recommendation may be positive or negative, conditional or unconditional reflecting current evidence and the understanding of the guideline group.

• A. Recommendation	There is robust evidence to recommend a pattern of care.
• B. Provisional Recommendation	On balance of evidence, a pattern of care is recommended with caution.
• C. Consensus Opinion	Evidence being inadequate, a pattern of care is recommended by consensus.

Exercise

The one RCT, enrolling 30 participants, comparing exercise with usual care provided some evidence that moderate-intensity exercise may reduce wandering. The group receiving exercise therapy showed a statistically significant reduction in wandering compared with control. However, this statistical significance was based on imputed SDs. Further, the outcome used to measure wandering was unclear. Also, the quality of this study was uncertain, as randomisation and concealment of allocation could not be confirmed as adequate and blinding of the outcome assessors was not reported. Also, the duration of the study was short (4 weeks).

We found some evidence for the effectiveness of exercise therapy, but as this has been provided by only one study of low quality and has not been confirmed by independent trials, this evidence must be regarded as of low quality.

Special care units

Overall, the two non-RCTs, enrolling 129 participants, evaluating special care units provided no robust evidence about the efficacy of this intervention; one study[49] found significantly less wandering among patients in traditional units, whereas the other study[50] found non-significantly less wandering among patients in special care units.

TABLE 2 Summary of the quality of the studies and grade of evidence using the GREG scheme

Type of intervention	Number of		Number of participants	Mean duration of follow-up (weeks)	Quality marker		Baseline comparability[a]	Blinding of outcome assessor	Grade of evidence[b]
	RCTs	Non-RCTs			Randomisation description	Concealment of allocation			
Multi-sensory environment	3[c]	0	198	5	2 (67%)	1 (33%)	0 (0%)	0 (0%)	Low
Music	1		30	1	0 (0%)	0 (0%)	0 (0%)	0 (0%)	Low
Exercise	1		30	4	0 (0%)	0 (0%)	1 (100%)	0 (0%)	Low
Special care unit	0	2	129	12	0 (0%)	0 (0%)	2 (100%)	0 (0%)	Low
Aromatherapy	2		84	5	2 (100%)	0 (0%)	1 (100%)	2 (100%)	Low
Behaviour management	0	1	21	7	0 (0%)	0 (0%)	–	0 (0%)	Low

[a] Assessed for parallel trials only.
[b] Using GREG.[42]
[c] Findings of two trials were combined in a meta-analysis; the third trial reported no wandering in either group.

We found no evidence for the effectiveness of special care units; the evidence identified was of low quality.

Aromatherapy with essential oils

Overall, the two RCTs, enrolling 84 participants, comparing essential oils with control oils provided no robust evidence about the efficacy of this intervention. One study[46] found that patients receiving essential oils showed significantly less wandering behaviour, but this finding was of marginal statistical significance ($p = 0.05$) and was based on an approximate allowance for clustering of patients within nursing homes.[64] The other study[52] found no difference in wandering behaviour between patients receiving essential oils and those receiving control oils.

We found no robust evidence for the effectiveness of aromatherapy; the evidence identified was of low quality.

Individualised behaviour management programme

The one non-RCT, enrolling 21 participants, evaluating individualised behaviour management programmes provided no evidence that this intervention reduced wandering. Patients in the control group were less likely to wander than those receiving the individualised behaviour management programmes, but it was unclear whether this effect was statistically significant as SDs of the effect of treatment were not reported.

We found no evidence for the effectiveness of individualised behaviour management; the evidence identified was of low quality.

Results of the systematic review of economic studies

A thorough literature search of economic studies or clinical studies containing relevant economic information was conducted. The sources searched, the search strategies and data extraction have been detailed in Chapter 2 and Appendix 3.

None of the studies retrieved investigated the cost-effectiveness of the intervention strategies, and no cost information about the interventions was reported in the studies included in the clinical review.[43–50,52,53] However the clinical studies[43–50,52,53] did provide some data on the resources utilised to deliver the intervention and the comparator. Further information was sought from the authors in order to undertake a parallel

costing exercise. However, no further details on either the resources used or the costs involved were received by 31 March 2005.

The search also retrieved literature on tangible and intangible costs of behavioural symptoms in dementia, which encompassed wandering but were not specific to it.[65–72] The paper by Calkins[67] reported on an article which appeared in 1984 in a specialised magazine (*Nursing Home Security and Safety Management*). The extra costs that a wandering resident posed to a long-term care facility budget were estimated at up to US$2000 per year. This figure included the additional time required by staff for supervision, search and retrieval of a person who wandered. The study by Foxwell[66] referred to the claims for elopement liability made by the relatives of people who wandered while in long-term institutions. The study reported that 10% of all claims made against long-term care facilities were elopement-related, for which an average expense of US$100,000 was estimated. However, both of these address costs of care in the USA and may not be relevant to care settings in the UK.

Two articles reviewed key studies which estimated the costs of dementia care in general,[68,69] including an overview of the annual costs of care of AD.[68] The comprehensive review by Wimo and colleagues[69] highlighted the great variability of the costs of dementia care reported in the literature. None of the studies included in these two reviews[68,69] provided information on costs specific to wandering behaviour. Wimo and colleagues drew attention to the difficulty of estimating the value of the resources needed, and in particular informal carers' opportunity costs, to manage behavioural disturbances.[69] They took as an example wandering behaviour, and underlined the methodological development for estimating the value of supervision required for up to 24 hours.

The remaining three studies retrieved were original investigations and provided estimates of the impact of symptom severity on the cost of care, taking into account behavioural disturbances overall.[70–72] Beeri and colleagues[70] conducted a survey among 71 community-dwelling people with AD in Israel. The authors determined the amount of time informal carers spent caring for the patients. The focus was on time spent on the management of behavioural and psychological symptoms, which included pacing. Primary caregivers spent 70 hours per month (33% of their caring activity time) on the management of behavioural and psychological symptoms. The

supervision required, namely the care provided to protect patients from harming themselves or others, was 30 hours per month (14.3% of the care-giving time).

Kirchner and colleagues[71] estimated the cost of care for people with dementia in a pilot study. Eleven subjects were supervised 24 hours per day. During a week, 80% of the hours of care were provided by an informal carer. If the care provided by the informal carer had been valued at the average rate paid by the Department of Social Services to professional carers, the mean cost would have been £1207 per person per week. The authors could not provide a breakdown of the time spent on tangible care and time spent on general supervision. The related costs could yield a different estimate, since these services are likely to be provided by different professional agencies.

O'Shea conducted a community-based study of 98 carers of people with dementia in Ireland.[72] The author reported that on average the carers spent 19.6 hours per day (SD 10.5) on supervision. Carers suggested a maximum reimbursement of €12.4 per hour for their caring activity, in comparison with the current national minimum wage of €5.5 per hour. For carers who had to give up work, the authors estimated a minimum net opportunity cost of €130 per capita per week.

Intangible costs of distress to informal carers as a consequence of behavioural symptoms, including wandering, have been quantified in a study recently completed by three of the authors of this report.[73] Other 'utility' studies have been reported in the literature;[74–78] however none of them addressed specifically wandering symptoms.

Unfortunately, lack of cost-effectiveness results and the paucity and poor quality of the clinical effectiveness data retrieved did not allow the intended modelling study, as part of the cost-effectiveness study, to be undertaken. A pragmatic decision was made, however, to utilise the acquired data to develop a framework for a Markov cost-effectiveness analysis model, which may be of help in future long-term research studies to provide insight into the complexity of decision-making and highlight areas of uncertainty. A description of the methods used to develop the framework and details of the additional epidemiological literature and costs of wandering behaviour required for inclusion in the framework of the model are presented in Appendix 8.

Summary of cost-effectiveness results

In conclusion, none of the studies retrieved in the systematic review evaluated the cost-effectiveness of the intervention strategies included in the clinical effectiveness review. Some literature was available on the tangible and intangible costs of behavioural symptoms in people with dementia, but it was not specific to wandering.

Chapter 4
Acceptability and ethical issues

This chapter presents the results for the acceptability and ethical issues associated with the use of the interventions. The first section presents the results from the systematic review and the second section presents the results from the discussion groups performed in the qualitative study.

Results of the systematic review

Characteristics of included papers: summary

Twenty-seven papers were included in the review; 10 discussed ethical issues,[26,79–87] 12 discussed acceptability issues,[65,88–98] and five both ethical and acceptability issues[99–103] (see Appendix 4 for a list of included papers).

By far the most common intervention discussed was the use of electronic devices such as tagging and tracking devices.[26,65,81–84,86–88,93,98,100–102] Other papers discussed physical barriers,[103] physical restraints,[79,80,85] planned walking,[90] hand massage[91] and environmental design.[94] A further five papers did not focus on any one intervention but discussed a mixture of interventions/strategies used by formal and informal carers.[89,95–97,99] These included interventions such as physical barriers, physical restraints, environmental modifications, reality orientation, massage/touch, music groups and exercise groups, in addition to carer strategies such as colluding with wrongly held beliefs, distraction or diversion tactics, reassurance and ignoring the behaviour.

Papers differed in their conceptualisation of wandering, and the specific behaviour under study, depending on the type of intervention being discussed. Whereas papers discussing tracking devices focused on getting lost outside the home and elopement,[65,84,86,93,100] those discussing tagging, physical barriers and environmental designs tended to focus on exit-seeking and attempts to leave.[81–83,88,94,95,98,101,102] Papers describing group activities defined wandering in terms of aimless walking or disruptive wandering into other people's rooms,[96,97] whereas those describing carer strategies referred to broader typologies such as

that used by Hope and Fairburn.[89,99] Papers relating to physical restraints did not provide any definition of wandering.[79,80,85]

The majority of the papers on ethical issues were discussion papers, mostly opinion based, and with little empirical evidence cited to support the arguments presented. The papers discussing acceptability issues were based on findings from non-controlled research or pilot studies (e.g. before-and-after studies, qualitative studies or surveys), but mostly with small convenience samples. Although these reported the views of informal (family) and/or formal (staff) carers, none included the perspective of the person with cognitive impairment as reported by themselves. In all the studies, assessment of acceptability was by subjective judgement rather than formal measures of quality of life and/or satisfaction.

Findings from the narrative review

The three main themes which emerged were:

- utility of intervention
- conflicting principles and values
- decision-making.

These themes have been compared across the different interventions to examine any differences or commonalities within them. However, it is important to note that one code ran through all three themes, that of safety and the prevention or reduction of harm, through considered risk assessment.

Theme 1: utility of intervention

Most papers discussed the utility of interventions, from the perspective of either formal (i.e. nursing, residential and day-care staff) or informal (or lay) carers. It should be noted that although carers also gave their perceptions of the utility of the different interventions on behalf of the person with dementia, none of the papers reported the perspective of the person with dementia as reported by themselves.

There were two main subthemes in this category:

- usefulness and/or acceptability
- problems and/or difficulties.

Tagging/tracking devices

Generally, both informal and formal carers were reported to have a positive response to the use of tagging and/or tracking devices, either in principle[93,102] or based on their experience from taking part in a pilot study.[65,88,98,100,101] The response to use of the devices by the people who wandered was reported to be variable; some objected to wearing the transmitter whereas others were said not to mind.[65,88] In response to the question 'would you want yourself to be tagged if you were incompetent to give your permission to do so?', 76% of carers in one study replied 'yes'.[102]

The main benefits of using the device were felt to be increased confidence and peace of mind for informal carers,[65,93,101] and a reduction in stress and release of time for other duties for staff.[102] The main benefit cited with regard to the person with cognitive impairment was that they would be located more quickly and more easily and so reduce their risk from harm.[65,93,102]

Problems for some informal carers included: cost[65] (although some carers would be willing to pay for such a device[93]), the extensive training and technical support required,[92] technical problems,[92] the size of the device,[100] difficulties fitting and remembering to test batteries[65] and the increased demand on informal carers in terms of using the equipment, monitoring and searching for their relative, especially if the carer was also elderly.[100] There was also increased demand on staff time when they had to accompany residents who wanted to leave the building.[98] In addition, some felt the devices gave a false sense of security, allowing people to go out when they where not safe; in effect, the devices did not abolish risk.[82,100,102]

Physical barriers/physical restraints

The use of physical barriers such as locked doors also helped to reduce anxiety for staff and carers. Secure residential facilities with space to wander safely were perceived to be beneficial to staff in terms of avoiding constant monitoring and spending more time on individual activities with residents.[103] Informal carers also locked doors to prevent their relative from wandering; however they expressed guilt when doing so and fear in case of fire.[89]

Physical restraints were sometimes felt to be necessary to safeguard residents as a temporary measure; however, there was uncertainty as to whether they were effective or safe. Papers cited the many negative psychological and physical effects of restraints, including injury and mortality, and it was generally felt that their use was not acceptable in the majority of cases.[79,80,85,99]

Environmental modifications

Modifications to the environment and design of buildings received a generally positive response from both formal and informal carers, depending on the alterations made. Use of environmental cues such as arrows and signs were deemed both acceptable and useful in reducing wandering.[95,96,99] Other aspects felt to be helpful included increasing the space available for wandering, providing a calm, safe and home-like environment and reducing stimuli.[94,95] However, some design features, such as the layout of the building, caused problems for staff in terms of making monitoring more difficult and actually encouraged exit-seeking.[94] Low-density units also reduced stimulation and increased restlessness in some residents.[94]

Music groups

Carers reported that people with dementia exhibited overt signs of appreciation for music therapy although it needed to be focused on individual preferences.[97]

Exercise/walking

Planned walking was judged to have been successful and enjoyable for residents, increasing both physical and social stimulation.[90,96] Participants in exercise groups also slept better and there was less disruption to other residents.[97] Nursing staff reported feeling more relaxed and less worried when participating residents were out on walks, and being more able to attend to needs of other residents.[90]

Massage

Use of massage and touch was generally felt to improve relationships and interaction between the person with dementia and carers, in addition to calming agitation and reducing wandering in a small number of clients.[91,99] It was perceived that the majority of clients found it enjoyable (based on facial expressions, etc.) and carers also found it beneficial in terms of feeling calm and relaxed.[91] However, not all clients liked the treatment and sensory stimulation could increase agitation in some people. Staff also found it difficult to devote time to the scheme if they were short staffed.

Multi-sensory stimulation

Although no papers were directly identified in the narrative review pertaining to this intervention, reviews of the three studies[44–46] included in the

clinical effectiveness review provided some relevant information. In the study by McNamara and Kempenaar,[45] researchers recorded observable short term effects on relaxation, pleasure and communication and that the participants seemed to be enjoying the interventions. In the other two studies,[43,44] participants related better to others and were less bored[44] and there were improvements in communication.[45]

Behavioural interventions

Reality orientation was not felt to be helpful unless the cause of the wandering behaviour was obvious. Both formal and informal carers found that it could actually increase distress, fear and agitation in the person with dementia, therefore it was not deemed to be an acceptable strategy to manage behaviour.[89,95,99]

Carer strategies (collusion, distraction, reassurance, ignoring)

Informal carers felt that diverting their relative with 'safe' and meaningful activities (e.g. housework) and 'pottering' were acceptable strategies to manage wandering,[89] whereas nursing staff found that getting to know residents' personal history helped them to understand the behaviour.[95] Some nursing staff also found validation and reminiscence to be appropriate ways of promoting understanding of residents' needs.[99] The use of reassurance was felt to be effective when the person was fearful or agitated.[89,95] In general, strategies needed to be tailored to the individual and modified as the disease progressed.[95] Conversely, both formal and informal carers felt that the use of collusion and meaningless distraction (such as folding paper), although often effective in the short term, ultimately were unacceptable strategies for managing wandering behaviour.[89,99]

Theme 2: conflicting principles and values

There was no discussion of conflicting ethical principles in the papers describing music groups,[97] walking/exercise groups,[90,97] massage/touch[91,95,99] or reality orientation.[89,95,99]

A number of conflicting ethical principles were discussed in relation to tagging and/or tracking devices,[26,65,81–84,86–88,93,98,100–102] physical barriers,[103] restraints,[79,80,85] environmental design[94] and carer strategies.[89,95–97,99] These included tensions between the principles of beneficence ('doing good') and non-maleficence ('avoiding harm'), and between safety and rights to autonomy, liberty, dignity and privacy, that is,

the balance between societal/legal values versus person-centred/individual values.

The main argument surrounding the principle of beneficence concerned whose 'best interests' were being considered. 'Best interests' was more often discussed in terms of protection from harm (non-maleficence), both for the person who wandered and others who may be harmed by them.[83,84] Some papers discussed the balance between acting in the best interests of the person who wandered and those of the other residents[83] or even the institution itself.[87]

The conflict between the person's right to autonomy or liberty and the need for safety or security was discussed in most of the papers on the use of tagging and tracking, physical barriers and restraints. Some argued that the person's right to autonomy should be balanced against the risk of harm both to themselves and to others.[79,80,84,85,103] For example, although the use of physical restraints reduces the person's autonomy, it was argued that other residents also have the right to freedom from interference and/or harm.[79] Nursing philosophy incorporates the promotion of safety and protection from harm;[80] however, responsibility for the person's safety in situations when movement cannot legally be restricted (i.e. residents who have voluntary status and are not detained under the Mental Health Act) led to nursing dilemmas.[99] One paper noted that although the present social climate favours the rights and autonomy of the individual, the medical profession is more likely to favour 'the right to safety over freedom'.[86] Nurses are also fearful of litigation, although this fear has so far proved to be unfounded.[79]

The tension between the use of surveillance and the person's right to privacy was discussed in a few papers, with some arguing that it was a breach of privacy[26,87] and others arguing that this was only the case if the person was trying to hide.[84] There were also differing views with respect to the impact of electronic devices on the dignity of the person. Such devices may increase the stigma attached to people with dementia because of the connotations of tagging with the criminal justice system,[83] but it was also argued that the use of such devices is neither 'degrading nor dehumanizing'.[84] A survey of formal and informal carers reported that only 18% of respondents thought that tagging would reduce a person's dignity.[102] Concerns that the use of electronic devices would reduce staffing levels or interaction with residents were cited in some papers.[82,83] Others argued that the devices would

increase rather than decrease interaction with residents.[81] In general, electronic devices were widely regarded as the least objective and restrictive intervention.[81–84,101]

With respect to environmental modifications, there was tension for professional carers between the promotion and prevention of wandering, but such interventions were considered important in promoting person-centred values and potentially improving quality of life.[94]

Theme 3: decision-making

There were two main subthemes in this category:

- involvement in decision-making
- justification for decisions.

Involvement in and control of decision-making regarding the interventions was discussed in papers relating to electronic devices,[26,65,81–84,86,88,93,98,100–102] physical barriers and restraints,[79,80,85,103] massage and touch[91] and carer strategies.[89,95–97,99] Whereas formal carers stressed the need for a team approach and joint decision-making involving all relevant parties,[95,99] family carers tended to make their own decisions based on personal experience of what worked.[89] Informed consent was a particular issue in papers on tagging and tracking, physical barriers and restraints. Most noted that informed consent should be obtained either from the person who wanders or a reliable proxy, as tagging without informed consent is illegal and may constitute an assault.[82] The use of physical barriers and restraints without consent may also be legally restricted.[99,103] However, the use of restraints was considered justified if serious harm was prevented and this superseded the person's right to refuse;[85] sometimes family carers found it difficult to contest when such decisions were made by professional carers.[79] There was also some discussion about capacity to consent and whether or not the person with dementia really understood what they were agreeing to.[100,103] Some residents were confused by the concept of a locked facility.[103]

Justification for decisions varied between interventions. Electronic devices tended to be justified in terms of them being 'the least restrictive form of restraint' both to the person who wanders and to other residents, and being 'more humane' than physical or chemical restraints.[81,83,84,86,101] Interestingly, in one study, none of the informal carers who had used the electronic device felt they would give their relative

more freedom. Rather than using the justification that the device would maximise the person's autonomy, it was used on the basis of a reduction in the time until their relative was found, hence reducing the risk of harm.[100]

Physical barriers such as locked doors were sometimes justified as a means of allowing the person with dementia to wander within a secure area.[103] However, family carers justified their use in that they provided a way of coping, for example allowing the carer to sleep in cases of nocturnal wandering and reducing the need for continuous supervision.[89]

Justifications for use of physical restraints included fear of litigation, reduction of risk of injury and insufficient staff to cope with the behaviour.[79,80,85] However, all the papers cited evidence that restraints can cause physical and mental harm and in some cases even death. Therefore, the risks of using such restraints have to be weighed against the risks of not using them.

Papers reporting environmental design/modifications,[94–96,99] walking/exercise groups[90,97] and massage/touch[91,95,99] tended to justify their use in terms of benefits to the person with dementia and their carers. These included decreased agitation/wandering, reduced disruption to other residents and improved interaction and relationships.[90,91,95–97] On the other hand, informal carer strategies such as ignoring the behaviour or collusion with wrong beliefs were justified in terms of carers' coping mechanisms.[89]

No justification of decisions was discussed for the use of music groups,[97] or reality orientation.[89,95,99]

Summary of ethical/acceptability findings for the systematic review

The perspectives of people with dementia as reported by themselves towards the acceptability of the interventions could not be determined from the systematic review as the included literature focused on carers' views and proxy reports.

Acceptability and usefulness of the interventions
Most acceptable interventions
Walking/exercise groups, music groups and diverting people with meaningful and safe activities such as housework were perceived by formal and lay carers to be the most acceptable approaches to managing wandering. Although the results of our systematic review demonstrated little evidence of effectiveness for these approaches,

they were perceived to be enjoyable and beneficial for the people with dementia and the carers who participated. Getting to know residents' personal histories was also perceived to be a useful and acceptable strategy for nursing staff to understand wandering behaviour and for appraising appropriate approaches to its management.

Acceptable interventions with some limitations
Electronic devices, environmental modifications or designs and massage/touch were generally perceived by formal and informal carers to be acceptable interventions to manage wandering, although some reservations were expressed. With regard to tagging and tracking devices, these included a number of technical and practical difficulties, increased demand on carers' time and the cost of the devices. Some environmental designs such as the location of doors and windows and low-density units were found to encourage exit-seeking and increase restlessness in some residents. Likewise, massage/touch could increase agitation in some residents.

The use of physical barriers such as locking doors was perceived to be helpful to formal and informal carers in terms of reducing anxiety and allowing them to spend time on other activities. In institutional settings, such approaches were seen as essential for managing and protecting groups of residents; however, family carers expressed guilt about their use and fear that their relative could come to harm in the event of a fire.

Unacceptable interventions
The use of physical restraints, reality orientation and collusion were perceived by formal and informal carers to have negative effects on the person with dementia and therefore to be unacceptable strategies to manage wandering.

Ethical implications of the interventions
Interventions with no associated ethical issues
There was no discussion of conflicting ethical principles in papers describing walking/exercise groups, music groups, massage/touch or reality orientation. Although this finding might be expected for walking/exercise and music groups which were perceived to be more acceptable interventions to manage wandering, it is more surprising for reality orientation, which was perceived to have negative or harmful consequences for the person with dementia.

Interventions with limited ethical issues
There was limited ethical discussion surrounding environmental designs and carer strategies. For

environmental designs, this mainly focused on the conflict between the need for staff supervision/surveillance and the need for space and privacy. Tensions between promoting safe wandering and the prevention of harm were raised in relation to both approaches to management of wandering.

Interventions with considerable ethical issues
A number of conflicting ethical principles were discussed in relation to tagging and tracking devices, physical barriers and physical restraints. These mainly centred on the tension between the person's right to autonomy or freedom to wander and the need for security or safety. With regard to restraints and barriers, these ethical dilemmas were concerned with the restrictive nature of the interventions and the emphasis on the prevention of wandering. For tagging and tracking devices, the main ethical concerns surrounded the use of surveillance and the rights to autonomy, privacy and dignity and the stigma associated with the use of such devices. There were also concerns that the use of such devices would reduce staffing levels or interaction with residents, although no evidence of this has been reported.

Decision-making about the use of the interventions
Informal and formal carers appeared to make decisions about the use of interventions to manage wandering in different ways. Family carers seemed to make these decisions on their own, based on personal experience of what worked. Strategies tended to be justified in terms of carers' coping mechanisms, having 'no other option' and the prevention of harm, rather than maximising autonomy for the person with dementia.

Formal carers stressed the need for a team approach and joint decision-making involving all relevant parties. There was concern about informed consent from the person with dementia or a reliable proxy with respect to the use of physical restraints, barriers and electronic devices but not for any of the other interventions. Use of interventions was often justified in terms of balancing risks and benefits, usually risk of harm against maximising autonomy. The use of physical barriers and restraints tended to be justified in terms of preventing wandering and therefore injury, whereas electronic devices, environmental designs and walking/exercise groups were mainly justified in terms of promoting safe wandering.

Results from the qualitative study

Content of group discussions

Task groups were held with three groups of stakeholders (*n* = 13) who had experience of managing wandering in dementia (healthcare professionals, formal carers and informal carers) to inform the findings of the review. A task group is a forum that enables relevant stakeholders to contribute to discussion about services and policies that may affect them.[57] They are designed to provide the opportunity for stakeholders to engage in informed debate about a particular issue from their own perspectives, usually with the aim of arriving at a decision or recommendation after a process of deliberation. Groups were therefore presented with the findings of the review and asked to consider the following study questions:

1. How useful and acceptable are the different types of approaches?
2. What are the ethical problems of the different approaches?
3. What principles would you wish to see considered in the development of such approaches?
4. What outcomes are meaningful to people with dementia and their families?

An exploratory focus group was also held with a group of people with mild dementia (*n* = 6) to discuss some of the issues arising from the review. This group was necessarily shorter in duration and less structured than the task groups as this was thought to be the most relevant approach for people in the earlier stages of dementia. The information presented focused on only one intervention, the acceptability or otherwise of tagging and tracking devices.

Study questions and emergent themes

1. How useful and acceptable are the different types of approaches?

Four subthemes emerged from the discussion of this question:

- familiarity of use
- context
- usefulness and/or benefits
- negative consequences and/or problems.

Tagging/tracking devices

Although none of the participants had direct experience of using electronic tagging and tracking devices, informal carers felt that technological and non-technological methods of surveillance, such as closed circuit television (CCTV) and community watch groups, were commonly used and accepted in society. Health professionals and formal and informal carers agreed that electronic tagging and tracking devices would be most useful in community settings for people who had a carer available, as they would give peace of mind to carers and enable them to locate the person and bring them back.

> "When my father wandered off and was brought back I thought it would have been ideal if he'd had something in his pocket that I could have phoned up and got the coordinates exactly where he was. I'd have just got in the car and gone off and picked him up."
>
> Informal carer 2

It was also felt that electronic tagging would be useful in hospital settings, so that patients could not wander out of wards undetected. However, such devices were not felt to be as useful in nursing or residential homes with people with more severe dementia and problems were anticipated if there were insufficient staff to answer the alarm. Health professionals also expressed concern about the over-use of such devices at the expense of other (more personal) approaches to care, simply because the technology was available. This had been experienced with the introduction of door intercom systems, which were installed for many people but which they could not or did not actually use. Formal carers felt that tagging devices were often associated with criminal offenders.

The participants with dementia were not familiar with using new technologies such as mobile phones (some of which have recently been developed to incorporate tracking devices) and said they would find the use of such technology confusing, difficult to learn and distracting.

> "It would be more confusing when you're walking along and this thing it would be more distracting you (all agree)."
>
> Person with dementia 1

They also expressed concern that tracking devices could be embarrassing if they omitted a noise when they were out in public, and that mobile phones used as tracking devices could be stolen from them. Familiarity of use of the intervention was of paramount importance to this group. For example, participants felt they would be happy to carry identity cards because they were used to carrying them during the Second World War.

Physical restraints and barriers

None of the participants felt that physical restraints were an acceptable approach to manage

wandering. Some formal carers had witnessed the use of Geri-chairs and other types of restraint in people's own homes, however, and felt that sometimes this was the only way carers could manage the behaviour.

> "A neighbour I know had an elderly demented relative living with them and I was quite appalled when I went in and the lady was actually in one of those chairs in the corner of the sitting room and couldn't get out but it was the only way she could manage her."
>
> Formal carer 6

Both the health professionals and formal carers noted that physical restraints such as Buxton chairs used to be a common approach to manage people with dementia; however, they were no longer used in nursing and residential care settings. Bean bag chairs were sometimes used in nursing homes, but to prevent people with walking difficulties from falling rather than to prevent wandering. Likewise, reclining chairs were sometimes used to give wanderers a rest and said to prevent injury rather than preventing wandering *per se*. However, informal carers felt that the use of such restraints in nursing homes was a reflection of poor staffing levels and noted that some residents in nursing homes were put into wheelchairs because of insufficient staff and subsequently lost the ability to walk/wander.

The use of locked doors, keypads and alarms was said to be common throughout society, because of crime and personal safety reasons, and not just specific to dementia care. Health professionals and informal carers believed that people with dementia were commonly locked inside their homes to prevent them from wandering, even though they could be at risk if there was a fire. Formal and informal carers noted that most nursing homes operated a locked door policy, usually because the residents were in the more severe stages of dementia and did not have sufficient skills to be able to go outside unaccompanied.

> "You can't expect the staff to be forever running round checking that the patients haven't gone on the wander. For their own safety and for the peace of mind of the staff your building has got to have a secure outside door. I think that is absolutely essential. Other methods of restraint are not acceptable but the building itself should be secure."
>
> Informal carer 1.

Locked doors also prevented other people from entering the building. Informal carers felt

that locking outside doors was essential in the management of people who wander, so that staff would not have to keep checking on residents and to keep the building secure. However, it was felt that inside doors and possibly the door to the garden should be unlocked. Health professionals were concerned that locked doors might make people feel imprisoned and increase agitation and the feeling that they need to get out. Furthermore, locked doors were not always effective, as people could break the windows to get out.

Environmental designs
Environmental designs and modifications such as wandering pathways and gardens generally met with a positive response from participants, although health professionals felt that they were more appropriate in specialist assessment or residential/nursing home settings rather than general hospital wards. All participants felt that people with dementia would benefit from having space to wander safely. However, some health professionals felt that long corridors could make people feel disorientated, and one formal carer described how an internal walkway had to be blocked off owing to a number of untoward incidents between residents (physical and sexual attacks). In this instance staff had to divide the area using a keypad system, even though blocking off the walkway led to increased agitation in some residents who were no longer able to wander freely around the building.

Purpose-built garden areas were deemed particularly beneficial for people who wander as they can give pleasure, provide a normal activity, allow people to be outside in natural daylight and help aid sleep in the evenings.

> "We've got a huge garden and we've got two doors, one from the lounge and one from the dining room, which we leave the alarms off. And people just wander if they want to and you notice a massive difference in their behaviour whether it's winter or summer. Summer time when they can get out and enjoy the sunshine, what a difference."
>
> Formal carer 2

Health professionals and formal carers noted, however, that gardens could only be used if there were sufficient staff to supervise residents because of safety concerns (risk of falling).

> "I think the gardens are there but you can't go out because it's too wet or it's too cold or we can't spare the staff to be with you or you might fall."
>
> Health professional 3

Distraction activities (e.g. music, activity and walking groups)
Distraction activities were said to be commonly used in residential and nursing homes. Informal carers felt that music groups could help prompt memories and be enjoyable for residents. They also thought that participation in religious services might be beneficial for some people. Conversely, formal carers found that distraction activities only worked for a short period because of poor attention levels and that increased stimulus (such as music groups) could increase agitation and aggression in some residents.

> "Sometimes it has the reverse effect though because often we do groups and we have musical afternoons sometimes and by the end of the day it's just wild really you know, everyone's so agitated, so aggressive. No-one sleeps at night."
>
> Formal carer 6

Health professionals felt that walking groups could be beneficial and the participants with dementia agreed that walking kept them fit, relieved tension, was an enjoyable activity and preferable to being kept indoors. However, one health professional had found that providing carers to go out walking with people was expensive, particularly 'out of hours', which meant paying overtime rates.

Sensory therapies (e.g. multi-sensory environment, aromatherapy)
Most formal and informal carers were familiar with multi-sensory rooms, which were sometimes used in conjunction with massage. These were felt to help calm agitation in some residents but were not used specifically to reduce wandering (although people could wander in or out of the room as they pleased). However, these rooms were often not used because the staff did not have the correct training.

> "I don't think they had anybody that was really trained to use it [sensory room] because the people need to know how to massage, but I think sometimes even just to put people in the room with all the lights and everything, I thought it was fantastic."
>
> Informal carer 3

Behavioural therapies (e.g. reality orientation, ABC approach)
Some health professionals were familiar with the ABC approach (i.e. determining the antecedents, behaviour and consequences of wandering) and stressed the importance of getting to know the person and their personal history to help understand and manage the behaviour.

> "Why do they go out when they do and where do they go and a fair amount of detail on that, you know what happens beforehand, what are they doing, what the consequences are. I would probably do that and I certainly have done that with several people. And very much looking at past behaviours so is the wandering actually purposeless or is it actually something they've always done."
>
> Health professional 3

Formal carers felt that reality orientation was more useful in the earlier stages of dementia or when the wandering was purposeful, such as trying to get 'home' or to work. For people in the later stages, it was felt that general reality orientation, for example, to the day or time, was acceptable but that specific reality orientation could have very negative effects on residents, causing great distress for some. Staff preferred to tell 'white lies' than answer some direct questions and risk upsetting residents.

Carer strategies (e.g. collusion, distraction)
Formal carers tended to use their experience, knowledge of the person or simply trial and error to determine the best approach to use with a resident. Both health professionals and formal carers used distraction as their main strategy with people in the later stages of dementia, as it was felt that residents tended to wander aimlessly or had a compulsion to move with little insight into what they were doing. Informal carers said they tended to 'play along' or collude with their relative's beliefs.

> "You couldn't do anything but play along with it and of course the more you could keep her engaged in conversation the less she was likely to wander."
>
> Informal carer 1

2. What are the ethical problems of the different approaches?
Three subthemes emerged from discussion of this question:

- conflicting principles
- person-centred values
- societal/legal values.

In general, discussion centred on the conflict between safety and the prevention of harm and the freedom to wander and maintain independence. Getting the balance right between what is or is not regarded to be an acceptable risk was perceived to be difficult, and conflicting perspectives of risk (e.g. between relatives and staff) could be hard to reconcile. Staff were afraid of being sued if someone was injured or died in

their care and a constant compromise was made between what was best for the person and the protection of staff within the organisation. However, informal carers felt that this meant some residents were over-protected. It was also felt to be difficult to balance the rights of the individual against the rights of residents as a whole.

Ethical problems tended to be discussed in relation to electronic tagging and tracking devices and the use of physical restraints and barriers. Health professionals were cautious about the use of electronic surveillance devices which could become too intrusive, whereas informal carers disagreed about the person with dementia's rights to privacy.

> "In terms of being ethical I don't think I want to be in a situation where big brother's watching me all the time and I don't think I should be putting other people in that situation. I'm really not comfortable with it."
>
> Health professional 3

The participants with dementia said they would not want to be monitored all of the time, although this depended to some extent on who was doing the monitoring (e.g. spouse or social services). They also felt it should be the choice of the person with dementia whether or not they used such devices.

> "If someone was keeping an eye on you it would depend who it was. If it was your partner you might feel alright about it but you might not. You might not want your partner always to know where you were. It's the relationship you've got with the person who is keeping an eye on you."
>
> Person with dementia 3

Formal carers felt that the use of physical restraints such as Buxton chairs constituted an abuse of civil liberties; however, they acknowledged that other forms of restraint such as bean bag chairs were still used. In these cases it was felt that it was the intent or purpose of the restraint that was important (i.e. to prevent someone from falling rather than to restrict wandering).

> "I would think that the Buxton chair was totally illegal and abusing the person's civil liberties, but in saying that they do it in other ways, using a bean bag or locking the door."
>
> Formal carer 1

Both health professionals and formal carers felt that society would regard them as negligent if they didn't operate a locked door policy in homes or wards.

> It's a constant compromise between what's best for the individual but what you have to do to protect yourself within the organisation you work for as well."
>
> Formal carer 3

Informal carers agreed that residents should have the freedom to wander around the home and garden but there was disagreement as to whether they should have the freedom to leave unaccompanied; this depended on the severity of the dementia. The participants with dementia stressed the importance of independence and choice to go outside for a walk.

No ethical problems were raised with regard to distraction activities, sensory therapies, environmental designs, behavioural therapies or carer strategies.

3. What principles would you wish to see considered in the development of such approaches?

Three subthemes emerged when discussing principles which should underpin approaches to manage wandering:

- design/planning
- decision-making
- person-centred.

Formal and informal carers felt that staff, carers and people in the early stages of dementia should be involved from the beginning in the design and/or planning of interventions to manage wandering. They also felt there should be a consensus of agreement that an approach is to be implemented, which may require education and training for staff or carers.

> "Getting the people higher up in the planning process on our side and involving us and carers and patients and other groups like that."
>
> Formal carer 3

With regard to the interventions, it was recommended that they be simple to use, relatively inexpensive and, in the case of new technologies, unobtrusive and fail-safe.

Health professionals and formal carers stressed the need for multi-disciplinary decision-making when considering use of an intervention, involving family carers and the person with dementia where possible. Furthermore, it was felt that any decision should be fluid, regularly reviewed and able to change as the person or the situation changes. All participants felt that an individualised person-centred approach based on the history, choice and

risk assessment of the person should be taken. A blanket approach was not recommended (e.g. everyone being tagged); rather, approaches should be matched to the person and may change over time.

> "I think an individualised multi-disciplinary approach, including relatives and perhaps the users themselves and maybe raising the issues with the people before they become or in the early stages of dementia about how they want to be treated in the future."
>
> Health professional 2

4. What outcomes are meaningful to people with dementia and their families?
Four themes emerged from discussion of this question:

- quality of life of the person with dementia
- quality of life of carers
- quality of life of other residents
- safety.

All participants felt that quality of life was the most meaningful outcome for people with dementia and their carers. It was felt that this should be measured in terms of the improvement of well-being, happiness and participation in activities rather than longevity of life *per se*.

> "Outcomes might be people's participation in activities and so on. That might be something that we could be looking to increase. For example, attendance at reality orientation or reminiscence groups or something might be regarded as a positive outcome as opposed to counting the number of times they rattle on the door. Because it sounds as though if someone is wandering they are not involved, they are not attached, they are not involved with what is actually happening in the place that they are living."
>
> Health professional 2

Participants also felt that the quality of life of carers (formal or informal) was also an important outcome. It was felt that this should be measured in terms of the reduction of carer stress and physical and mental well-being.

> "I think it's a massive problem for people who are at home and in the early stages and it must be a real massive problem for the carers, so stressful. So I think in that respect they would really want something that was workable to help them for the stress levels more than anything."
>
> Formal carer 1

Health professionals suggested that the quality of life of other residents should also be considered. This could be measured in terms of the reduction

of resident stress and untoward incidents (e.g. physical attacks).

> "One of the other things that we haven't mentioned is the affect of wanderers on other residents in a home. If you've got one person who wants to be on the go all the time, how that affects everybody else."
>
> Health professional 3

All participants felt that the physical safety of the person was an important outcome. This could be measured in terms of the reduction of accidents or injuries.

> "I guess physical safety would be an important outcome for family members, you know if they are not with them. Thinking about tagging or tracking, they are interested in what's happened to my family member, have they been out, have they fallen and have they walked into a fast moving road? So maybe your outcome measure or your aim is not to stop somebody wandering but to enable them to do it in a way that might keep them a little bit safer."
>
> Health professional 1

Summary of acceptability/ethical findings from qualitative study
Acceptability and usefulness of the interventions
Most acceptable interventions
Walking groups, purpose-built gardens and distraction techniques were perceived by health professionals, formal and informal carers to be the most acceptable and beneficial approaches to managing wandering. Establishing the person's history, antecedents and consequences of their wandering behaviour prior to management was considered very important. Participants with dementia perceived exercise and identity cards to be the most useful and acceptable approaches for people in the early stages of the disease.

Acceptable interventions with some limitations
Electronic devices, locked doors, wandering pathways, sensory rooms, music groups and general reality orientation were mostly perceived by health professionals and formal and informal carers to be acceptable and beneficial interventions to manage wandering, although some reservations were expressed. Electronic devices were generally felt to be useful in community and hospital settings, providing peace of mind for carers and enabling them to locate the person who wandered. However, there were concerns about the associated criminal connotations, overuse at the expense of more personal approaches to care and sufficient staff to respond to an alarm in institutional settings. The participants with dementia felt that use of

unfamiliar technology would be confusing, difficult to learn and distracting, and that such devices could be embarrassing and may place them at risk.

Locked external doors were generally felt to be necessary in residential and nursing home settings, but could increase agitation in some residents. Space to wander safely was considered to be beneficial; however, long corridors could disorientate residents and make it difficult to monitor interactions and untoward incidents. Music groups and specific reality orientation, although potentially useful, could also increase agitation in some people in the later stages of dementia. Sensory rooms were considered acceptable and useful in calming agitation, but were not specifically used to reduce wandering.

Unacceptable interventions
The use of physical restraints to manage wandering was perceived to be unacceptable by all participants; however, bean bag and reclining chairs were considered by formal carers to be useful in the prevention of falls/injuries.

Ethical implications of the interventions
Interventions with no associated ethical issues
No ethical issues were raised with regard to distraction activities (e.g. walking and music groups), sensory rooms or therapies, environmental designs, behavioural therapies or carer strategies.

Interventions with limited ethical issues
There was limited ethical discussion around the use of locked doors. This mainly focused on the conflict between facilitating freedom and independence and ensuring safety and protection from harm; however, a locked door policy was considered the norm in society and not specific to dementia care. There was also concern about professional negligence if a locked door policy was not in operation and the person came to any harm.

Interventions with considerable ethical issues
A number of ethical issues were discussed in relation to tagging and tracking devices and physical restraints. With regard to electronic devices, these mainly centred on the use of surveillance and the person's right to privacy and choice. Physical restraints were felt to constitute an abuse of civil liberties, although the intent or purpose of the restraint was felt to be an important mitigating factor in their use.

Underlying principles and outcome measures recommended for future research
Underlying principles
1. Involvement of relevant stakeholders, including carers and people in the early stages of dementia, in the design and planning of interventions.
2. Involvement of relevant stakeholders, including carers and people with dementia where possible, in decision-making about the use of interventions.
3. Interventions should be matched to the individual, using a person-centred approach based on the wandering history, stakeholder preferences and a considered risk assessment of the individual situation.

Outcome measures
1. Quality of life for the person with dementia measured by an improvement in well-being and participation in activities.
2. Quality of life of formal and informal carers measured by a reduction in carer stress and improvement in physical and mental wellbeing.
3. Quality of life of other residents measured by a reduction in resident stress and untoward incidents.
4. Physical safety of the person with dementia measured by a reduction in accidents and injuries.

Summary of acceptability and ethical issues

There was considerable consensus between the findings of the narrative review and the qualitative study. From both practical and moral perspectives, the most acceptable interventions were distraction therapies such as walking/exercise and diversion tactics. These interventions were found to be acceptable in both the findings of the narrative and the qualitative review and so were categorised 'most' acceptable. All other interventions were generally considered acceptable with some reservations, apart from physical restraints which were deemed unacceptable. There was some discrepancy between the two methodologies with regard to reality orientation and collusion; in the narrative review these approaches were unacceptable but participants in the discussion groups felt they could be potentially useful. Considerable ethical concerns exist to the use of electronic tagging and tracking devices and physical restraints. Theoretically concerns also exist with the use of physical barriers but practically, 'locked doors' now appear to be an

acceptable and necessary aspect of society in general and therefore not a specific issue in dementia care. The acceptability of interventions may vary as the severity of dementia progresses.

Existing literature does not address the perspectives of people with dementia on the acceptability of non-pharmacological interventions to prevent wandering in dementia. However, the small number of people with dementia who participated in the qualitative study all felt that walking kept them fit, relieved tension and was an enjoyable activity. The use of unfamiliar technology, such as mobile telephones, would be confusing and place them at risk; however, the use of familiar objects such as identify cards was acceptable to them. *Table 3* provided an overall summary of the acceptability/ethical findings for each of the considered interventions.

TABLE 3 *Summary of acceptability and ethical issues related to the use of non-pharmacological interventions to reduce wandering*

Intervention	Acceptability	Ethical issues	Specific comments
Walking/exercise	Most acceptable[a]	No ethical issues raised	People with dementia, carers and health professionals very positive about usage Increase physical and social stimulation for people with dementia
ABC approach	Most acceptable[a]	No ethical issues raised	Health professionals and formal carers very positive about usage Helps to understand the person's wandering behaviour
Distraction techniques	Most acceptable[a]	No ethical issues raised	People with dementia, carers and health professionals very positive about usage Increase physical and social stimulation for people with dementia
Music therapy	Acceptable	No ethical issues raised	People with dementia (proxy report by carers) and carers very positive about usage May increase agitation in some people with dementia
Massage/sensory rooms	Acceptable	No ethical issues raised	Improve relationships between people with dementia and carers May increase agitation in some people with dementia
Environmental modification	Acceptable	Some ethical issues	Some design features can increase exit seeking or agitation Conflict between promotion of wandering and ensuring safety
Electronic devices	Acceptable	Considerable ethical issues	Help to reduce carer anxiety Practical and technical difficulties; user compliance Conflict between surveillance and privacy, loss of dignity; stigma
Physical barriers	Acceptable	Considerable ethical issues	Help to reduce staff/carer anxiety Allow carers to do other activities Conflict between safety issues and patient freedom and autonomy
Reality orientation	Acceptable	No ethical issues raised	May be useful with people in early stages of dementia Can increase distress and agitation in people in later stages of dementia
Collusion	Unacceptable	No ethical issues raised	Felt to be useful in short term by carers but ultimately unacceptable
Physical restraints	Unacceptable	Considerable ethical issues	Concern about effect on person with dementia Conflict between fear of litigation if used against being sued if not used and person is harmed; abuse of civil liberties

[a] These interventions were found to be acceptable in the findings of both the literature review and the focus groups.

Chapter 5
Conclusions and discussion

Statement of principal findings

The main findings of this systematic review are summarised below.

Effectiveness of non-pharmacological interventions to reduce wandering

There is no adequate, good-quality evidence from controlled trials to recommend the use of any specific non-pharmacological intervention to reduce wandering in people with dementia.

There is some evidence, albeit of poor quality, for the effectiveness of exercise to reduce wandering in people with dementia. However, as this was provided from an inadequately reported, single study and assumptions had to be made in its interpretation, this evidence must be regarded as of low quality.

There is some evidence, albeit of poor quality, that a multi-sensory environment may result in a small reduction in wandering in people with dementia immediately after therapy sessions, but it is questionable whether this reduction is of practical importance and would continue over a long period. This evidence was from pooling the results of two studies and not from individual studies.

Cost-effectiveness of non-pharmacological interventions to reduce wandering

The cost-effectiveness of the interventions included in the review could not be determined owing to the lack of cost information in the clinical and economic literature reviewed.

Acceptability of non-pharmacological interventions to reduce wandering and the ethical issues associated with their use

There was considerable consensus between the findings of the narrative review and the qualitative study. From both practical and moral perspectives, the most acceptable interventions were distraction therapies such as walking/exercise and diversion tactics. All other interventions were generally considered acceptable with some reservations, apart from physical restraints, which were deemed

unacceptable. Considerable ethical concerns exist over the use of electronic tagging and tracking devices. Theoretically concerns also exist with the use of physical barriers, but practically, 'locked doors' now appear to be an acceptable and necessary aspect of society in general and therefore not a specific issue in dementia care. There was some discrepancy between the findings of the two approaches with regard to reality orientation and collusion; in the narrative review these approaches were unacceptable but participants in the discussion groups felt they could be potentially useful.

The perspectives of people with dementia, as reported by themselves, towards the acceptability of the interventions could not be determined from the narrative review as the literature only included carers' views and proxy reports. However, the small number of people with dementia who participated in the qualitative study felt that walking kept them fit, relieved tension and was an enjoyable activity. They stressed the importance of maintaining their independence and the need for autonomy. All felt that the use of unfamiliar technology, such as mobile telephones, would be confusing and place them at risk; however, the use of familiar objects such as identify cards was acceptable.

The process of decision-making regarding the use of interventions was important, especially for interventions associated with considerable ethical conflict such as electronic devices, physical barriers and restraints, but also for interventions involving personal contact such as massage. Decision-making should include securing valid consent from the person with dementia (or a reliable proxy), multidisciplinary involvement including lay carers and where possible the person with dementia, and a considered risk assessment of the balance between the benefits and the risks of using the intervention. Establishing the person's history, antecedents and consequences of their wandering behaviour prior to management is necessary.

The concept of risk assessment in managing wandering was an important theme; with both lay and formal carers mindful of the need to balance

TABLE 4 *Summary of the effectiveness and acceptability/ethical issues for non-pharmacological interventions to reduce wandering in dementia*

Intervention	Effectiveness	Quality of evidence for effectiveness	Acceptability	Ethical issues
Walking/exercise	Significant reduction in wandering with exercise	Low	Most acceptable	No ethical issues reported
Multi-sensory environment	Some evidence for effectiveness with pooling of results	Low	Acceptable	No ethical issues reported
Music therapy	No evidence for effectiveness	Low	Acceptable	No ethical issues reported
Special care unit	No evidence for effectiveness	Low	No data	No ethical issues reported
Massage/touch	No relevant studies included	–	Acceptable	No ethical issues reported
Aromatherapy	Significant reduction in wandering in one study	Low	No data	No ethical issues reported
Electronic devices	No relevant studies included	–	Acceptable	Considerable ethical issues
Physical barriers	No relevant studies included	–	Acceptable	Some ethical issues
Environmental modifications	No relevant studies included	–	Acceptable	Some ethical issues
Reality orientation/collusion	No relevant studies included	–	Unacceptable	Some ethical issues
Physical restraints	No relevant studies included	–	Unacceptable	Considerable ethical issues

a person with dementia's right to autonomy with their professional duty to minimise harm. Lay carers exhibited greater tolerances of risk with professional carers wary of litigation. It is important to note that the use of some interventions such as tagging and tracking devices did not abolish risk for carers.

Table 4 summarises the conclusions of both the effectiveness and acceptability/ethical data for the interventions included in the review.

Strengths and limitations of the review

The strengths of this systematic review include the following:

- The systematic review brings together the evidence for the effectiveness of non-pharmacological methods to prevent wandering in dementia, together with an assessment of

ethical and acceptability issues associated with their use.
- The review was guided by the principles for undertaking a systematic review, applying consistent methods of critical appraisal and presentations.
- The methods of the review were outlined in a research protocol (Appendix 1) before the review commenced, which defined the methods and process to be used.
- The conception, development and completion of the review were informed by an advisory group (see Acknowledgements).
- The review includes both quantitative data (effectiveness and cost-effectiveness) and qualitative data (ethical and acceptability issues and stakeholder perspectives).
- The systematic review benefited from the input of a variety of external experts of varied background (medicine, nursing, psychology) and geographical location.
- Users' views on the results of the systematic review were obtained through the inclusion of a

qualitative study which involved discussion groups with relevant stakeholders.

- The specific use of task group methodology in the qualitative study allowed stakeholder views on the results of the effectiveness data to be determined.
- The qualitative study included people with mild dementia, whose perspectives are currently ignored in the existing literature.

However, there were limitations to the study, as follows.

Systematic review

It was difficult to follow up with authors of included studies with respect to additional data that may have been useful in determining effectiveness.

Ten studies were included in the clinical effectiveness review (seven RCTs and three non-RCTs). A quality assessment of the studies was difficult as the reporting of the studies was generally poor. Six reported the size of the treatment and comparator groups. Blinding of the outcome assessors was confirmed in only two. Among the seven RCTs, the randomisation process was adequate in only two.

Twenty-seven papers were included in the review of acceptability/ethical issues. The papers considered for acceptability generally reported original research such as qualitative studies, pilot projects and surveys. However, the majority of papers reviewed for consideration of ethical issues were opinion-based discussion papers.

There is no definite methodological consensus regarding the synthesis of qualitative and quantitative data within a systematic review, with a variety of approaches suggested, and in fact many reviews do not consider qualitative data. The approach selected, determined after a methodological literature review and discussion with the project team, was felt to meet best the objectives of the study.

There is a wide variety of systems to grade the quality of evidence and hence determine the strength of recommendations. As yet, no one system has been universally recommended.[104] The GREG scheme[42] was used as the project team were familiar with its use and it allowed an overall assessment of the quality of the studies.

Cost-effectiveness study

The cost-effectiveness of the interventions included in the clinical effectiveness review could not be determined owing to the lack of cost-effectiveness results retrieved. In addition, the paucity and poor quality of epidemiological data on the consequences of wandering and lack of related costs and evidence of effectiveness of the interventions limited the development of a model to provide longer term cost-effectiveness estimates. There is a need for more information on the types and prevalence of injuries as a consequence of wandering and elopement both within a community setting and institutionalised care in order to inform cost-effectiveness.

Qualitative study

The qualitative study involved a small number of participants. Data collection was limited by time constraints and not determined by data saturation.

It was difficult to recruit people with dementia for one-to-one interview; however, a focus group was successfully completed as an alternative to seek their views. Compared with the task groups, the focus group was by necessity, shorter and less structured and a limited amount of information was presented.

Other issues for discussion

Prevention of wandering versus promotion of safe walking

Over the last decade, there has been increasing recognition that wandering may have beneficial effects for people with dementia, providing exercise, improving circulation and promoting more regular sleep patterns,[27–29] although the evidence is not strong.[105] This is corroborated by the findings of our small qualitative study. The focus of this systematic review was the prevention of wandering rather than the promotion of safe wandering or walking. Findings from both the narrative review and the discussion groups suggest that the perspectives of health professionals and formal carers may differ from the views of people with dementia; the latter stress the importance of independence and autonomy and the promotion of safe wandering, whereas the former are primarily concerned with the prevention of harm. Lack of information on the actual risks involved, that is, accurate data on the types and prevalence of injuries as a consequence of wandering and elopement, would lead to better informed decision-making and a more realistic assessment of risk. This in turn may produce a shift in management approach, which is shared by both people with dementia and their carers, towards

the promotion of safe wandering and appropriate interventions to facilitate this.

The use of regular exercise, simple environmental modifications (e.g. signs, arrows) and educating carers in techniques such as the ABC approach and distraction methods could limit unsafe wandering and may prevent or delay both the use of more unacceptable interventions and entry into institutionalised care.

Definition of wandering

As outlined in Chapter 1, there is no clear definition of wandering and it is more often represented through a typology. The term incorporates a diverse spectrum of behaviours that have been categorised in several ways (i.e. according to geography, frequency and purpose[4,8] and relationship to neurocognitive deficit[10]). Of the 235 studies identified as potentially relevant to include in the review, almost half were excluded as it was not possible to identify clearly any of the relevant behaviours represented in the typology of wandering and wandering *per se* was often subsumed within the term agitation or agitated behaviour. Of the ten studies included in the effectiveness review, only four defined their understanding of the concept of wandering.[48,49,52,53] All four used different definitions and only one used a previously referenced definition.[48] The remainder did not provide a definition but wandering/aimless walking/pacing was included as an outcome measure in the study.[43–45,47]

Outcome measures

The lack of specificity and clarity in the definition of the term wandering was reflected in the range of outcome measures used in the included studies. Some studies included validated instruments such as the NPI,[32] which had subscales relevant to wandering; others used non-validated measures. Future studies should acknowledge this limitation and instead of attempting to measure the actual behaviour should focus on the consequences of wandering (e.g. number of exits from home, number of entries into other residents' rooms, number of police notifications of missing persons) and the physical well-being of the person with dementia (i.e. physical injuries sustained, number of hospital admissions). In addition, studies should incorporate more meaningful outcomes for both people with dementia and their carers which reflect a more positive approach to wandering, such as the desired quality of life in terms of well-being and participation in activities.

With regard to the economic outcomes, reporting of cost-effectiveness data was poor both in terms of the development and running costs of the interventions and the costs incurred to health, social and emergency services as a consequence of wandering behaviour. Identification of the significant consequences of wandering, which were mutually agreed by all stakeholders, including people with dementia and carers, would assist in highlighting key and relevant economic costs to be measured. Such measures may include, for example, getting lost (police and emergency services notification), physical injuries sustained (hospital admission, attendance at Accident and Emergency department), and entry into institutional care (costs of formal community care incurred prior to entry).

Availability of new information

During the study, we identified ongoing studies with unpublished data and emerging interventions that may necessitate an update of this review within 24 months.

GPS-enabled mobile telephones

The New Technology in Elderly Care (NTEC) Project in London is evaluating the use of a GPS-enabled mobile telephone to locate people with dementia.[106] Initial results have revealed an accuracy of location within approximately 5 m. However, the main problem was user compliance. Out of 11 patients involved, five stopped participating owing to usability or comfort issues, mainly owing to the bulkiness and weight of the telephone.[106] The development of such technology is in contrast to the views of the small number of people with dementia who participated in this study who did not use and would not consider using mobile telephones. GPS technology is also being incorporated into other methods such as locator wrist watches, which may be more acceptable to people with dementia.

Telecare systems

Telecare is the use of sensing technology to monitor remotely a client's environment and give warning of any hazards such as gas leaks, falls or wandering. Sensors are fitted within the person's 'home' and either connected to a central control unit monitored by a warden in sheltered accommodation schemes or in domestic premises connected to a community alarm service. For a person who wanders, the device consists of a door contact and keypad, thereby alerting the carer if the person leaves the home. In addition, bed pressure sensors can provide an earlier warning device for carers. Sensors can be fitted under the

mattress of a bed or under the castors to detect if a person wanders at night. A Telecare pilot study is currently under way in the UK using a variety of Telecare devices and sensors, including a wandering alarm (Champion C, ICES Advisory Board, Newcastle upon Tyne, personal communication, 2005). Houses may be adapted with the use of multiple sensors, including door exit sensors, bed pressure monitors and fall detectors, to create 'smart homes.'[107]

Therapeutic touch

A randomised, double-blind Canadian study, enrolling 57 residents in special care units, which examined the effect of therapeutic touch on the frequency and intensity of behavioural symptoms in dementia, has recently been completed following a successful pilot study.[108] The main outcome measure was overall behavioural symptoms in dementia. These consisted of six categories of behaviour including restlessness, pacing and walking, searching and wandering, and escape restraints. Results revealed a significant difference in overall behaviour in the experimental group.

Implications for healthcare

There is no robust evidence so far to recommend the use of any non-pharmacological intervention to reduce or prevent wandering in people with dementia. The Committee on the Safety of Medicine's recommendations that certain neuroleptic drugs should not be used to manage behavioural problems in people with dementia[23] will further promote the use of non-pharmacological methods and the need to determine the effectiveness of such interventions will be essential. If such interventions were found to be effective, then positive outcomes may include reduced anxiety and stress for carers, improved quality of life for both people with dementia and their carers and, for people with dementia living at home, reduced or delayed institutionalisation.

Increasing recognition that wandering may have positive and therapeutic effects for people with dementia (such as increasing exercise, improving sleep patterns, relieving boredom and enhancing quality of life) may lead to a culture shift from the 'prevention of wandering' to the 'promotion of safe walking'. A spectrum of interventions which encourage the former rather than prevent the latter, and hence facilitate a more person-centred approach in dementia care, would be required.

Recommendations for research

From the results of this review, the following recommendations for research are suggested.

Quantitative research

Recommendation
There is a need for high-quality studies to determine the clinical effectiveness and cost-effectiveness of non-pharmacological interventions that allow safe wandering and are considered practically and ethically acceptable by carers and people with dementia. Such interventions include walking/exercise, music therapy (most acceptable) aromatherapy, massage, multi-sensory environments and environmental modifications/design (acceptable).

There is a need for large-scale, long-term cohort studies to evaluate the morbidity and mortality associated with wandering in dementia for people both in the community and in residential care. Further research is required to ascertain specifically the impact of wandering behaviour on costs of care both in the community and in formal care settings.

Provisional recommendation
As there was some evidence, albeit of low quality, demonstrating the effectiveness of planned walking/exercise, and as this was considered one of the most acceptable interventions, future quantitative research should initially be focused on this intervention. This would also underpin the ethos of promotion of safe walking rather than prevention of wandering.

Where possible, studies should be RCTs; however, such studies may be difficult where the study samples are in institutionalised care and cluster randomisation would provide a useful alternative. The majority of studies included in the effectiveness review had small sample sizes, did not define the specific aspects of wandering behaviour to be studied and used a wide variety of often non-validated outcome measures. Future studies should include sample sizes from which appropriate conclusions can be drawn and should state clearly the specific behaviour being studied; appropriate and specific outcome measures could then be selected.

Outcome measures in future studies
The diversity of behaviours incorporated in the term 'wandering' should be acknowledged. Outcome measures in future studies should focus on:

- the consequences of wandering, for example, the number of successful elopements, number of police notifications of missing persons
- the physical safety of the person with dementia (e.g. the number and nature of physical injuries, number of hospital admissions)
- participant-centred outcomes that reflect the desired quality of life for both people with dementia and their carers, and also the acceptability of the intervention.

Qualitative research

Recommendations

There is a need to determine the views of people with dementia on the acceptability of non-pharmacological interventions to reduce wandering. This is particularly relevant for the use of assistive technologies. As the rapid development of relevant assistive technologies allows for a more diverse and sensitive range of electronic devices, research into users' views of their acceptability and feasibility should precede expensive and complex quantitative studies to evaluate their effectiveness, that is, the evaluation of complex interventions should follow recommended guidance such as the Medical Research Council framework for the development and evaluation of complex interventions.[109]

There is a need to explore in greater depth the process of risk assessment and management by carers for people with dementia who wander, in addition to evaluating the effectiveness and acceptability of specific interventions to promote safe wandering. Issues to be considered would include:

- What constitutes an acceptable risk to relevant stakeholders, namely people with dementia, lay carers and formal carers?
- How to manage the conflicting perspectives of risk between formal and informal carers?

Provisional recommendation

There is a need to explore with all relevant stakeholders the boundaries between walking, safe wandering and unsafe wandering. Such in-depth qualitative research would help identify a set of mutually agreed significant outcomes/consequences of wandering for which relevant and appropriate outcome measures could be determined. It would also provide better understanding of the different perspectives held by professional/lay carers' and people with dementia perspectives and may help facilitate a shift from the prevention of wandering to the promotion of safe walking.

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Contribution of authors

Contribution to the study

Professor John Bond (Professor of Social Gerontology and Health Services Research; dementia research) developed the protocol and provided methodological expertise in all aspects of the study. Professor Clive Ballard, Professor of Age Related Disorders; dementia research) provided methodological expertise in the development of the protocol and the clinical effectiveness study. Dr Lynne Corner (Alzheimer's Society Research Fellow; dementia research) contributed to data extraction in the systematic review, carried out data analysis and facilitated the qualitative study. Dr Heather Dickinson (Principal Research Associate; medical statistics) conducted the review of clinical effectiveness. Dr Tracy Finch (Senior Research Associate; health technology assessment) conducted the review of acceptability issues, carried out data analysis and facilitated the qualitative study. Dr Julian Hughes (Consultant in Old Age Psychiatry; ethical issues in dementia) conducted the review of ethical issues and carried out data analysis. Ms Deborah Hutchings (Research Associate; dementia research) was the main researcher on the project. She conducted the systematic review, carried out the data extraction and analysis, facilitated the qualitative study and prepared the report for publication. Professor Carl May (Professor of Medical Sociology; health technology assessment) provided methodological expertise for analysis of the qualitative data and

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Appendix 1

Methods from the research protocol

This project will combine a systematic review, a modelling study and an exploratory qualitative study.

Systematic review

A systematic review of experimental (e.g. RCTs), non-RCTs and observational studies (e.g. case–control and cohort studies) and narrative review, to assess the clinical effectiveness and cost-effectiveness, acceptability and ethical issues of the listed technologies. In this context, the question of acceptability and ethical issues might be better dealt with by narrative or critical reviews in which key problems are identified, rather than trying to draw conclusions from a body of literature that may not be useful. In addition, acceptability and ethical concerns will be explored in more depth through a qualitative study described below.

Studies
Types of studies to be included: RCTs, non-RCTs, case–control studies and cohort studies, full economic evaluation and costing studies. Narrative review for evaluation of acceptability and ethical issues.

Participants
People with dementia of any type and age who exhibit wandering behaviour (defined as 'a tendency to move about in either a seemingly aimless or disorientated fashion or in pursuit of an indefinable or unobtainable goal').

Setting
Any care environment (home, hospital, other institution).

Type of Intervention
1. physical barriers, e.g. alarms, locks
2. physical restraints, e.g. ropes, tethers, Buxton chairs
3. electronic/technological devices, e.g. electronic tagging and tracking devices, alarm pads to detect movement from bed or other electronic means of monitoring
4. behavioural interventions, e.g. cognitive behavioural therapy, cognitive rehabilitation and reality orientation, multidisciplinary team interventions, carer interventions
5. prevention/distraction activities, e.g. music therapy, physical activity, planned walking, wandering areas
6. alternative therapies, e.g. homeopathy
7. sensory therapies, e.g. aromatherapy, Snoezelen, grouping music.

Trials of combinations of two or more of the above interventions will also be considered, as will studies published in any language.

The following interventions will not be included: pharmaceutical and subjective barriers.

Control or comparator treatment – usual care, that is, whatever criteria of care were in place before the particular interventions. This may involve a combination of methods (such as nurse/carer observation, medication, locked doors) and may be different in different studies.

Outcome measures
1. Primary outcomes – prevention/reduction of wandering (number of attempted exits, number of successful exits)
2. Secondary outcome measures – accidents (number and nature), deaths, reassurance for relatives (satisfaction/acceptability measures), quality of life for patients and informal carers (quality of life measures, patient anxiety/distress), cost of care (supervision needed, burden of informal care, prescription of drugs, use of health and social services either as a direct result of wandering, e.g. falls, fractures or side-effects of treatment). In addition, costs related to the technology adopted and its implementation (start-up costs and follow-up costs), including equipment, supervision, advice/training to carers, concomitant prescription of medication.

Search strategy
The search strategy will include electronic database searches, followed by handsearches in relevant literature sources such as reference lists from primary and review articles, journals, grey literature and conference proceedings and research registers.

Electronic database searches

The CD CIG specialised register will be searched (this contains RCTs and CCTs from the following sources, CCCTR/Central, MEDLINE (1966–2004), EMBASE (1980–2004), PsycINFO (1987–2004). In addition, MEDLINE, EMBASE, PsycINFO, CINAHL, British Nursing Index, OMNI (Organising Medical Networked Information), the HTA Programme database, CRD NHS Economic Evaluation database (NHSEED), OHE Economic Evaluation Database (HEED), National Research Register, SCISEARCH, Ageline, Healthstar will be searched for relevant primary studies. SIGLE (System for Information on Grey Literature), NTIS (National Technical Information Service) First search for government documents, CAN Research Index, Conference Paper Index, British Reports, Translations, CRD DARE, Current Contents – Clinical Medicine, and others will be searched to identify grey literature, such as dissertations and theses, and conference proceedings. For ethical issues, Bioethicsline, Philosopher's Index, RN+CN Journal Index, Uncover and Web of Science Social Index will also be searched. Appropriate current search terms and a structured search strategy will be determined through discussion with the review team and an information expert. These may be refined and combined differently as the searches are developed. Possible examples of search terms are given below:

Set 1 Cognitive impairment
([cognit$ or memory] adj2 [impair$ or declin$ or disorder$ or disturb$ or confus$])
or dement$ or Alzheimer's
Set 2 Wandering
exit$ or wander$ or ambulat$ or escap$ or elopement
Set 3 Interventions
Intervention$ or prevent$ or behavio$ or therap$ or manag$ or
exercis$ or aroma$ or music$ or educati$ or tagg$ or track$ or electri$ or restrain$ or lock$ or Buxton
Set 4 Methodology
RCT or [random$ adj^2 control$ systematic review$]

The literature of economic evaluations and costing studies will be retrieved by using an adapted template of the NHS Economic Evaluation Database search strategies[38].

Additional literature searches

The reference lists from primary studies and review articles identified through the electronic searches will be scanned to identify further studies for consideration. In addition, key journals in the field will be hand searched. Personal communication with specialists in the field to identify any further relevant unpublished data and 'grey literature' will follow when the search is completed. This will be done through identifying relevant studies and contacting first-named authors for any sources of unpublished data. A list of studies that meet the inclusion criteria will be sent to both an internal and an external subject expert to check the list for completeness. Updated searches will be required throughout the project. All identified literature will be catalogued and tracked using REFMAN bibliography software.

For economic evaluations, studies will be selected independently by the health economist and the Researcher Associate (RA[1]). They will be included in the review if they are (a) studies costing the intervention strategies or wandering behaviour or (b) full economic evaluations assessing the intervention strategies.

Review strategy
Study selection
All abstracts (or titles if not available) will be read independently by two reviewers (RA[1], RA[2]) to discard irrelevant articles. These two pools of relevant articles will be merged and the full articles obtained. Independent review of the full articles, applying the relevant inclusion/exclusion criteria, will be carried out by RA[1] and RA[2]. Any disagreements will be resolved by discussion with a third assessor from the study team. A list of excluded articles will be maintained.

Data extraction
Each study will be independently assessed by two assessors, RA[1] and one other member from the project team with nominated responsibility, LR, HD, LC, AV (health economics), TF (acceptability), JH (ethical issues), to determine its methodological quality, following criteria used by Cochrane EPOC Group for RCTs, NHS CRD report 4*, CRD Guidance for writing critical summaries of economic evaluations,[38,110] and other relevant checklists for quality assessment.[37] Information extracted is likely to include: article type; year; country; study type; setting; sample details; type of intervention, its theoretical basis and components, process and outcome measures.

Quality assessment
In addition, the following criteria will be applied for RCTs: adequacy of randomisation, individual or cluster randomisation, concealment of allocation, blinding of outcome assessors,

comparability of treatment groups at baseline and whether reported data are analysed on an intention-to-treat basis. We will contact authors for any data required for analysis which is not reported. Differences in judgement will be resolved through consultation with a third reviewer. Poor quality studies will be excluded in a sensitivity analysis. The usefulness of quantitative approaches for appraising the quality of economic evaluations[111–113] will be explored and methods will be applied as appropriate.

Acceptability and ethical issues

Increasingly, critics argue that health and technology assessment studies must pay greater attention to the social, political and ethical issues associated with technologies[114,115] and that the perspectives of patients and their carers and relatives should be given greater emphasis.[116] Such issues are particularly important in considering the overall effectiveness of interventions to manage wandering amongst people with dementia, owing to the potential ethical and social implications of these interventions. Narrative data and empirical data on these outcome measures will be extracted independently by two reviewers (without masking study site or author) using data extraction forms agreed by the team. Acceptability of the interventions will be determined by assessing the evidence obtained within individual studies concerning acceptability/degree of satisfaction from both patients' and carers' perspective, by considering (i) outcomes reported and (ii) the methods by which these were assessed. Data extracted from individual studies will be synthesised to address the following questions:

- Do patients and carers appear to find these interventions acceptable?
- Are some interventions viewed as more acceptable than others? (if so, which?)
- To what extent is the quality of evidence about the acceptability of these interventions adequate for informing decisions about the use of such interventions?

It is anticipated that few trials will include a formal assessment of the ethical implications of their interventions, although ethical issues are likely to be raised and discussed within publications in an informal way. To supplement the systematic review, additional papers relevant for the consideration of ethical arguments concerning wandering interventions will be sought and included in the narrative. With respect to ethical issues, the data extractors will look for

words indicating ethical issues. These might by particular terms (e.g. good) or ethical principles (e.g. autonomy) or other expressions pointing towards value judgements. The use of moral concepts or constructs will be noted.[117,118] It is likely that a variety of ethical viewpoints will be found and these recorded for later synthesis. We shall be alerted to the possibility that ethical judgements have been noted in the literature by their authors.

Data synthesis

The data will be collated and summarised by the tabulation of study characteristics and results and use of statistical methods if appropriate. If fewer than three controlled trials are identified, their findings will be summarised in a critical narrative but no formal statistical analysis will be performed. If three or more controlled trials are identified, their results will be combined in a formal meta-analysis. For continuous outcomes (e.g. satisfaction/acceptability, quality of life measures), the standardised weighted mean difference will be used to estimate effect sizes in individual trials and these will be aggregated to obtain a pooled effect size and its 95% CI. For dichotomous outcomes (e.g. low/high level of wandering), relative risks (RRs) will be calculated and used to calculate a pooled effect size.[51] Trials of behavioural interventions in a community setting are often randomised on the basis of groups rather than individuals. For such cluster RCTs, if the analysis accounted for the cluster design then a direct estimate of the desired treatment effect will be extracted, e.g. RR plus 95% CI. If the analysis did not account for the cluster design, an adjusted treatment effect will be estimated using an external estimate of the intracluster coefficient (ICC). It will then be possible to combine the cluster RCTs with individually randomised trials in the same meta-analysis, using generic inverse variance methods of meta-analysis.[119]

Heterogeneity between studies will be assessed both by visual inspection of Forest plots and by a formal statistical test for heterogeneity.[51,120] In the absence of significant heterogeneity, a fixed effects model will be used for the estimation of treatment effects. If there is evidence of significant heterogeneity, the possible reasons for this will be investigated and reported and a random effects model will be used. The possibility of publication bias will be investigated using funnel plots.[121]

Generalisability of results from studies conducted overseas will be addressed in relation to differences in health service systems, cost structures and issues

of cross-cultural validation of quality of life measures. Where studies of satisfactory quality and homogeneity exist, a meta-analysis of individual patient cost data will be undertaken.[122] Different methods for converting cost data to the UK currency will be tested.[123] The intervention costs will be compared to the savings accrued from a reduction in episodes of wandering, and the cost and effectiveness results for each relevant measure of benefit (e.g. exit, accident and death rates) will be summarised in a cost-effectiveness plane.[110]

Modelling study

Our scoping search suggested that the available evidence on the cost-effectiveness of the interventions may be too limited or of unsatisfactory quality to attempt a quantitative pooling of study findings. A narrative or critical review may equally reveal inadequate information. Under these circumstances, the economic evaluation will be undertaken as part of a simulation modelling exercise.[110,124]

If the evidence is inadequate to support definitive conclusions, two nested models will be constructed: a *disease epidemiological model* will consist of projected life-table or Markov-chain methods from detection of wandering behaviour to death. A binary structure will allow a direct comparison of each intervention strategy with standard care. A *costing model* will be developed to estimate the costs attributable to each event pathway for each relevant period. Patterns of costs will be estimated for different cohorts of patient groups, over a 10-year period. Covariates will include age, gender and residential setting. Depending on the specific model structure, cost-effectiveness may be estimated in terms of wandering-free months and life-years saved.

Data sources for the model

Whenever possible, suitable information on effectiveness and costs retrieved in the literature review will be used as parameter values or assumptions for the model. Additional 'ad hoc' sources may need to be explored to gather the necessary model data inputs. For example, observational studies based on longitudinal datasets from Medical Research Council Cognitive Function and Ageing Study (MRC CFAS) surveys will allow the estimation of the costs under usual care, by relating use of services and formal care to levels of cognitive impairment and wandering behaviour.[125] Estimates of costs of treating collateral effects due to the interventions may be gathered through experts' opinions. Costs of accidents because of wandering will be estimated

from a Centre for Health Services Research (CHSR) dataset on use of hospital services of people with dementia.[126] In this respect the model will be focused on costs to the hospital (emergency) services only, under the assumption that the use of primary care services is likely to be comparatively not relevant. Transition probabilities for entry into long-term care will be retrieved, reviewing the literature of wandering as a predictor of institutionalisation. Intangible costs of distress to carers will be quantified in utility scores currently being elicited in an ongoing study conducted by the applicants (Vanoli A and Bond J, Centre for Health Services Research, Newcastle upon Tyne, UK: personal communication, 2004).

Sensitivity analysis

Stochastic and non-stochastic uncertainties around the data estimates and model assumptions will be dealt with by the application of sensitivity analysis techniques in order to test the robustness of the results from the review or the model. The choice of the techniques will depend on the areas of uncertainty to be investigated, and the results will be plotted as cost-effectiveness acceptability curves.[127]

A final report of the review will describe the methods applied and the extent of the evidence base and summarise the overall effectiveness and cost effectiveness. It will discuss the implications for service providers and health policy, highlight the areas of uncertainty and identify issues for further research. Presentation of narrative analysis will take a qualitative form.

Qualitative study

From our scoping search, we anticipate a poor yield of literature to help determine consideration of the acceptability and ethical implications of the interventions. Therefore, a qualitative study, comprising of a series of focus groups and one-to-one interviews with relevant stakeholders, will explore these issues in more depth to inform and add weight to the results of the systematic review.

Qualitative data can be a valuable source of evidence in health technology assessments, although its contribution is commonly overlooked.[128] Conducted properly, qualitative research affords appropriate methodology to provide a theoretically grounded exploration of a complex topic. Initial results from the systematic review on the ethical issues presented by the use of the proposed interventions will be used to inform

a series of focus groups. These will be carried out by RA[2] and will include the following participant groups:

1. a range of health and social care professionals, for example, old age psychiatrists, community psychiatry nurses, clinical psychologists, general practitioners, community nurses, social workers.
2. formal carers, for example, nursing home and residential care staff, home care workers and care providers such as the Alzheimer's Society
3. informal carers, for example, spouses and relatives of people with dementia.

Participants in the focus groups will be presented with a summary of the initial findings from the systematic review and asked their opinion on the personal and moral acceptability of the individual interventions.

From the project team's extensive experience of qualitative research around dementia, focus groups are valuable for encouraging group discussion and reflection on a wide range of general issues; however they do not provide the most appropriate and sensitive setting to ascertain the personal views of people with dementia. Therefore, a series of one-to-one semi-structured interviews will be held to obtain their perspective. There is no consensus about appropriate sample size for qualitative research. Six to eight data sources often suffice for a homogeneous sample, whereas 12–20 may be needed when looking for disconfirming evidence. Sample size will be reviewed on an ongoing basis and sampling terminated when no new themes or concepts are elicited from the data collected. A purposive sample will be recruited to ensure a range of illness duration and age. Such interviews could be potentially distressing but LC (RA[2]) has extensive experience in this area.

Focus groups and interviews will be audio taped and transcribed in full. Anonymous transcripts will be analysed independently by RA[2] and RA[1] with support from LR and JB. Data analysis will go hand in hand with data collection. Each transcript will be analysed before proceeding to the next, looking for the emergence of theories and concepts and their testing using analytical induction.[58]

Appendix 2

Changes to the research protocol

Systematic review

The following changes, additions or points of clarification were made to the research protocol based on comments received from the advisory group and external experts (see Acknowledgements).

Inclusion criteria

1. Types of studies to evaluate effectiveness of interventions were expanded to include non-randomised trials, controlled before and after studies and observational studies. Studies to evaluate acceptability/ethical issues were expanded to include surveys of opinion, qualitative studies and discussion papers.
2. The participants included in the review were expanded to include people with acute or chronic cognitive impairment.[31] This included people with dementia, either unclassified or classified according to the major subtypes of vascular, Alzheimer's, mixed (vascular and Alzheimer's) and Lewy Body, in addition to people who are chronically cognitively impaired but do not fulfil the accepted criteria for the classification of dementia (e.g. people with mild neuro-cognitive disorder) and people with a syndrome of acute cognitive impairment (delirium), whether or not there is evidence of pre-existing chronic cognitive impairment.

The interventions considered for inclusion in the review were expanded to include environmental designs such as lighting and 'smart' homes. 'Cocoon' was added to the list of restraints.

Control or comparator treatment: (1) usual care, that is, whatever criteria of care were in place before the particular interventions. This may involve a combination of methods (such as nurse/carer observation, medication, locked doors) and may be different in different studies. (2) Sham therapy, which does not include the elements that the investigators believe to be effective in preventing wandering.

Outcome measures were expanded to include any measure of wandering (e.g. number of wandering occurrences, time until person is found, distance wandered/unit time, time spent not wandering, wandering as measured by subscales of psychiatric behaviour scales). Secondary outcome measures were expanded to include withdrawal from treatment as an indicator of tolerability.

Data sources and search strategy

1. The search terms were extended to include the following:
   Set 1: 'delirium', 'Pick', 'Huntington', 'Creutzfeldt', 'JCD', 'binswanger', 'Korsakoff', 'Wernicke', 'Lewy'
   Set 2: 'restlessness', 'pacing', 'walking', 'agitation', 'orientation', 'sun-downing'
   Set 3: 'alarms', 'barriers', 'cocoons', 'complementary therapies', 'snoezelen', 'sensory therapies', 'multi-sensory', 'environment', 'design', 'smart home', 'light', 'activities', 'distraction'.
   Set 4 Methodology: the RCT filter was removed to allow for non-RCT designs.
2. The sets of alternative terms were combined together, using relevant thesaurus headings and truncation as appropriate for each database.
3. The term 'agitation', which sometimes, but not always, includes 'wandering' as a subtype was included. There was concern about the number of additional references this would produce. It was agreed to conduct a pilot search including the term 'agitation' to determine whether or not it should be included in the review. This revealed a number studies for potential inclusion and the term was therefore included in the full search strategy.
4. Handsearches of relevant journals not covered by the Cochrane Collaboration were carried out, and included the *Journal of Dementia Care* (1999 to 2004) and *Dementia* (2002 to 2004).
5. The external experts were sent the list of studies that met the inclusion criteria (and those which had been excluded) to check the list for completeness, and to identify any further relevant unpublished data and grey literature.

Cost-effectiveness review

It was originally intended to include a simulation modelling exercise within the cost-effectiveness study and develop an epidemiological model, and associated costing model, nested within a Markov

cycle tree pathway for each event period. However, owing to the paucity and poor quality of the clinical, epidemiological and cost data retrieved, this could not be achieved. A pragmatic decision was made, however, to utilise the acquired data to develop a framework for a possible Markov model which may help inform future cost-effectiveness studies.

Qualitative study

As it proved to be difficult to recruit people with dementia for one-to-one interviews, a focus group was carried out instead with an established group of people with early dementia.

Appendix 3

Search strategies for individual databases

MEDLINE (OVID): 1966–April 2004
CINAHL (OVID): 1982–April 2004 week 1
CENTRAL (OVID) 2004 issue 1
Cochrane Library 2004 issue 1
1. MeSH headings: cognition disorders or delirium or (explode dementia)
2. ((cognit$ or memory) adj2 (impair$ or declin$ or disorder$ or disturb$ or defect$ or confus$)).tw
3. (dement$ or delir$ or alzheimer$ or pick$ or huntington$ or creutzfeldt$ or JCD$ or binswanger$ or korsakoff$ or wernicke$ or lewy$).tw
4. 1 or 2 or 3
5. MeSH heading: (explode walking)
6. wander$ or walk$ or pacing or pace$ or ambulat$ or escap$ or elop$ or orientat$ or agitat$ or restless$ or sun-down$ or sundown$
7. 5 or 6
8. tagg$ or track$ or alarm$ or electroni$ or restrain$ or lock$ or buxton or barrier$ or cocoon$ or complementary or snoezelen or snoozelan or aromatherap$ or sensory or music$ or exercis$ or environment$ or smart home$ or light$ or design$ or educat$ or manag$ or therap$ or behavio?r$ or activit$ or distract$ or prevent$ or intervention$
9. 4 and 7 and 8 (limited to human)

EMBASE (OVID): 1980–2004 week 14
Same search as MEDLINE with following alterations in thesaurus headings:
Cognition disorder = Cognitive defect

Science Citation Index and Social Science Citation Index: 1981–April 2004
ISI Proceedings: 1990–April
Current Contents (Clinical Medicine, Social and Behavioural Sciences)
1. TS=((cognit* or memory) and (impair* or declin* or disorder* or disturb* or defect* or confus*))
2. TS=((cognitive disorder* or cognition disorder* or dement* or delir* or alzheimer* or pick* or huntington* or creutzfeldt* or JCD* or binswanger* or korsakoff* or wernicke* or lewy*))
3. 1 or 2
4. TS=(wander* or walk* or pacing or pace* or ambulat* or escap* or elop* or orientat*

or agitat* or restless* or sun-down* or sundown*)
5. TS=(tagg* or track* or alarm* or electroni* or restrain* or lock* or buxton or barrier* or cocoon* or complementary or snoezelen or snoozelan or aromatherap* or sensory or music* or exercis* or environment* or smart home* or light* or design* or educat* or manag* or therap* or behavior* or behaviour* or activit* or distract* or prevent* or intervention*)
6. 3 and 4 and 5

PsycINFO: 1840–April 2004
(NB search syntax abbreviated for clarity)
1. Thesaurus headings de=(delirium or cognitive impairment or (explode dementia) or alzheimers disease or creutzfeldt jakob syndrome or picks disease)
2. ti/ab=((cognit* or memory) within 2 (impair* or declin* or disorder* or disturb* or defect* or confus*))
3. 1 or 2
4. ti/ab=(wander* or walk* or pacing or pace* or ambulat* or escap* or elop* or orientat* or agitat* or restless* or sun-down* or sundown*)
5. ti/ab =(tagg* or track* or alarm* or electroni* or restrain* or lock* or buxton or barrier* or cocoon* or complementary or snoezelen or snoozelan or aromatherap* or sensory or music* or exercis* or environment* or smart home* or light* or design* or educat* or manag* or therap* or behavior* or behaviour* or activit* or distract* or prevent* or intervention*)
6. 3 and 4 and 5

HEED: searched April 2004
1. dementia or delirium or cognit* or memory or alzheimer* or pick* or huntington* or creutzfeldt* or JCD* or binswanger* or korsakoff* or wernicke* or lewy*
2. (cognit* or memory) AND (impair* or declin* or disorder* or disturb* or defect* or confus*)
3. 1 or 2
4. exit* or wander* or ambulat* or escap* or elop*
5. intervention* or prevent* or distract* or activit* or behavio* or therap* or manag* or exercis* or aroma* or sensory or

complementary or music* or educat* or tagg* or track* or alarm or electroni* or restrain* or lock* or buxton or barrier* or cocoon*
6. 3 and 4 and 5

AgeInfo: searched April 2004
http://ageinfo.cpa.org.uk/scripts/ageinfo/hfclient.exe?A=AgeInfo&ae2=
dementia [KW] and (wandering or agitation or exit or escape or elope or environment or smart)

Ageline: searched April 2004
http://star.aarp.org/cgi-bin/starfinder/0?path=ageweb.txt&id=age1&pass=abcd&OK=OK
dementia [KW] and wandering behavior [KW]

ADEAR Alzheimers disease clinical trials database: searched April 2004
http://www.alzheimers.org/trials/index.html

Clinical Trials: searched April 2004
http://www.clinicaltrials.gov/
Browsed Dementia and then searched within this section for (wandering or agitation or exit or escape or elope)

CurrentControlledTrials.com: searched April 2004
http://www.controlled-trials.com/
dementia and (wander% or agitat% or exit% or escap% or elop% or ambulat%)

National Research Register: searched April 2004
http://www.update-software.com/projects/nrr/

dementia and (wander* or agitat* or exit* or escap* or elop* or ambulat*)

ZETOC: searched April 2004
http://etoc.mimas.ac.uk/zetoc/
Dementia and (wandering or agitation)

ETHX database: Kennedy Institute of Ethics, Georgetown University
http://uis-www-2.georgetown.edu/netahtml/ethx.htm
(exit$ or wander$ or ambulat$ or escap$ or elop$) and (intervention$ or prevent$ or distract$ or activit$ or behavio$ or therap$ or manag$ or exercis$ or aroma$ or sensory or complementary or music$ or educat$ or tagg$ or track$ or alarm$ or electroni$ or restrain$ or lock$ or buxton or barrier$ or cocoon$)

Bioethicsweb: Wellcome
http://bioethicsweb.ac.uk/
1. browsed relevant headings
2. keyword search (exit$ or wander$ or ambulat$ or escap$ or elop$)

Google, Zapmeta
Combinations of dementia and trial, randomi*, smart, environment.

BIOME
http://biome.ac.uk/
1. browsed relevant headings
2. keyword search (exit$ or wander$ or ambulat$ or escap$ or elop$)

Appendix 4
List of studies included in the review

Effectiveness studies

Baker R, Bell S, Assey J, Wareing L-A, Baker E, Gibson S, Dowling Z. *A randomised controlled trial of the Snoezelen multi-sensory environment for patients with dementia*. Bournemouth: Dorset Healthcare NHS Trust; 1998.

Baker R, Holloway J, Holtkamp CCM, Larsson A, Hartman LC, Pearce R, Scherman B, Johansson S, Thomas PW, Wareing LA, Owens M. Effects of multi-sensory stimulation for people with dementia. *J Adv Nurs* 2003;**43**:465–77.

Ballard CG, O'Brien, JT, Reichelt K, Perry EK. Aromatherapy as a safe and effective treatment for the management of agitation in severe dementia: the results of a double-blind, placebo-controlled trial with Melissa. *J Clin Psychiatry* 2002;**63**:553–8.

Frisoni GB, Gozzetti A, Bignamini V, Vellas BJ, Berger A-K, Bianchetti A, *et al*. Special care units for dementia in nursing homes: a controlled study of effectiveness. *Arch Gerontol Geriatr* 1998;**27** (Suppl 6):215–24.

Groene RW. Effectiveness of music therapy 1:1 intervention with individuals having senile dementia of the Alzheimer's type. *J Music Ther* 1993;**30**:138–57.

Ingersoll-Dayton B, Schroepfer T, Pryce J. The effectiveness of a solution-focused approach for problem behaviors among nursing home residents. *J Gerontol Social Work* 1999;**32**:49–64.

Landi F, Russo A, Bernabei R. Physical activity and behavior in the elderly: a pilot study. *Arch Gerontol Geriatr* 2004;(Suppl 9):235–41.

McNamara C, Kempenaar L. *A pilot study for comparison of specific sensory stimulation with multi sensory stimulation with people with dementia in a community setting*. Ayr: Ayrshire and Arran Primary Care NHS Trust; 2001.

Mitchell S. Aromatherapy's effectiveness in disorders associated with dementia. *Int J Aromather* 1993;**5**:20–3.

Swanson EA, Mass ML, Buckwalter KC. Catastrophic reactions and other behaviors of Alzheimer's residents: special unit compared with traditional units. *Arch Psychiatr Nursing* 1993;**7**:292–9.

Acceptability/ethical issues studies

Altus DE, Mathews RM, Xaverius PK, Engelman KK, Nolan BAD. Evaluating an electronic monitoring system for people who wander. *Am J Alzheimer's Dis* 2000; **15**:121–5.

Blackburn P. Freedom to wander. *Nurs Times* 1988; **84**:54–5.

Cantes S. and Rigby, P. Freedom to wander safely. *Eld Care* 1997;**9**:8–10.

Coleman EA. Physical restraint use in nursing home patients with dementia. *JAMA* 1993;**270**:2114–15.

Dawkins VH. Restraints and the elderly with mental illness: ethical issues and moral reasoning. *J Psychosoc Nurs* 1998;**36**:22–7.

Dodds P. Wandering: A short report on coping strategies adopted by informal carers. *Int J Geriatr Psychiatry* 1994; **9**:751–6.

Gaze H. An invisible leash? *Nurs Times* 1989;**85**:22–3.

Holmberg SK. A walking program for wanderers: volunteer training and development of an evening walker's group. *Geriatr Nursing* 1997;**18**:160–5.

Hughes JC, Louw SJ. Electronic tagging of people with dementia who wander: ethical considerations are possibly more important than practical benefits. *BMJ* 2002;**325**:847–8.

Kilstoff K, Chenoweth L. New approaches to health and well-being for dementia day-care clients, family carers and day-care staff. *Int J Nurs Pract* 1998;**4**:70–83.

Kinney JM, Kart CS, Murdoch LD, Conley CJ. Striving to provide safety assistance for families of elders. *Dementia* 2004;**3**:351–70.

Mapp S. Breaking bounds. *Commun Care* 1994;**2**:24.

Marr J. Electronic tagging. *Nurs Stand* 1989;**4**:54.

McShane R, Gedling K, Kenward B, Kenward R, Hope T, Jacoby R. The feasibility of electronic tracking devices in dementia: a telephone survey and case series. *Inter J Geriatr Psychiatry* 1998;**13**:556–63.

McShane R, Hope T, Wilkinson J. Tracking patients who wander: ethics and technology. *Lancet* 1994;**343**:1274.

Melillo KD, Futrell M. Wandering and technology devices: helping caregivers ensure the safety of confused older adults. *J Gerontolo Nurs* 1998;**24**:32–8.

Miskelly F. A novel system of electronic tagging in patients with dementia and wandering. *Age Ageing* 2004;**33**:304–6.

Morgan DG, Stewart NJ. The physical environment of special care units: needs of residents with dementia from the perspective of staff and family caregivers. *Qual Health Res* 1999;**9**:105–18.

Moss RJ, La Puma J. *The ethics of mechanical restraints*. Hastings Centre Report. 1991, January/February; 22–25.

Nicolle C. Issues in the use of tagging for people who wander: a European perspective. In *Proceedings of the conference working with vulnerable adults: innovative practice and technology in risk management, Belfast*. Belfast: Social Services Inspectorate, Department of Health and Social Services;1998. pp. 10–12.

Richter JM, Roberto KA, Bottenberg DJ. Communicating with persons with Alzheimer's disease: experiences of family and formal caregivers. *Arch Psychiatr Nurs* 1995;**9**:279–85.

Rosswurm MA, Zimmerman SL, Schwartz-Fulton J, Norman GA. Can we manage wandering behavior? *J Long-Term Care Admin* 1986;**14**:5–8.

Smith-Jones SM, Francis GM. Disruptive, institutionalized elderly: a cost-effective intervention. *J Psychosoc Nurs* 1992;**30**(10):17–20.

Anon. Wondering about the wanderers. *Lancet* 1994; **343**:1237–8.

Thompson M. How 'bracelets' can open doors. *Care Plan* 1998, September; 21–3.

Welsh S, Hassiotis A, O'Mahoney G, Deahl M. Big brother is watching you – the ethical implications of electronic surveillance measures in the elderly with dementia and in adults with learning difficulties. *Aging Ment Health* 2003;**7**:372–5.

Wilber KH, Machemer J. Balancing the competing values of freedom and safety in long-term dementia care: the Secured Perimeter Program. *J Ethics Law Aging* 1999;**5**:121–30.

Appendix 5
Studies excluded from the review

Papers not available for review

Ahoranta P, Virolainen A. The physical care environment: supporting functional ability and good life on demented patients [Finnish]. *Sairaanhoitaja (Helsinki)*, 2002;**75**(10):25–28.
Reason for exclusion: not available

Aud MA, Manion P, Hites KS. Elopement interventions for wandering LTC residents. *Long-Term Care Interface* 1931;**3**(12):26–9.
Reason for exclusion: not available

Gillogly B. Behavior management in senile dementia of the Alzheimer's type through exercis. PhD Thesis, University of California, Davis, 1991.
Reason for exclusion: not available

Haupt M, Karger A, Baumgartner D, Kuminoti D, Janner M, Schnieder F. Improvement of agitation and anxiety in dementia sufferers after psychoeducative training of their caregivers. *Fortschr Neurol Psychiatr* 2000;**68**:216–23.
Reason for exclusion: not available

Heptinstall D. Tagging: cause for alarm? *Working with Older People*. April 1998.
Reason for exclusion: not available

Hoeffer B, Rader J. 1989, Managing wandering behavior of cognitively impaired elderly in long term care facilities. NH, USA: National Center for Nursing Research; 1989.
Reason for exclusion: not available

Nicolle CA, Richardson SJ. Defining user requirements for people with dementia who wander. In *Proceedings of the European Conference on the Advancement of Rehabilitation Technology*, pp. 204–5.
Reason for exclusion: not available

Struble LM. Ambulation behaviors of people with Alzheimer's disease: case studies of residents on three facilities along the homelike continuum. Dissertation, University of Michigan, 1996.
Reason for exclusion: not available

Woolham J, *et al*. *The safe home project: using technology to support the care of people with dementia in their own home*. London: Hawker; 2002.
Reason for exclusion: not available

Papers excluded after detailed review

Drug treatment of agitation in dementia. Nurs Drug Alert, 1996;**20**(11):86.
Reason for exclusion: drug treatment

Electronics for wanderer security. *Contemp Long-Term Care*, 1987;**10**(5):56–9.
Reason for exclusion: descriptive only

High intensity light therapy in Alzheimer's disease [Sponsored by National Center for Complementary and Alternative Medicine (NCCAM) and National Institute on Aging (NIA)]; 2004.
Reason for exclusion: are looking at wandering/pacing but have no data yet

Special report. Electronic article surveillance systems in health care – an update, *Hosp Security Saf Manage* 1991; **11**(9):5–10.
Reason for exclusion: descriptive only

Abegg A, Wettstein A. Phototherapy of behavioral disorders as a sequela of disordered circadian rhythm in dementia in the elderly: difficulties in practical clinical applications. *Schweiz Arch Neurol Psychiatr* 1993;**144**:63–80.
Reason for exclusion: reports agitation and activity levels only – no data specific to wandering reported

Akhondzadeh S, Noroozian M, Mohammadi M, Ohadinia S, Jamshidi AH, Khani M. *Melissa officinalis* extract in the treatment of patients with mild to moderate Alzheimer's disease: a double blind, randomised, placebo controlled trial. *J Neurol Neurosurg Psychiatry* 2003;**74**:863–6.
Reason for exclusion: measures cognitive and global change (agitation as a side-effect); wandering not measured

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Reason for exclusion: measures sleep not wandering

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Reason for exclusion: reports physical agitation using CMAI but no actual data on pacing. No answer from authors

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Reason for exclusion: survey data only

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Reason for exclusion: data provided in study duplicated in other paper

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Reason for exclusion: includes drugs and not specific to wandering

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Reason for exclusion: no control group

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Reason for exclusion: reports mean overall CMAI scores only, no data specific to wandering

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Reason for exclusion: not specific to wandering; no separate control group

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Reason for exclusion: descriptive only

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Reason for exclusion: not wandering

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Reason for exclusion: measures behaviour changes, no data specific to wandering

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Reason for exclusion: not specific to wandering; no control group

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Reason for exclusion: no control group

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Reason for exclusion: review

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Reason for exclusion: reply from authors – no separate control group

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Reason for exclusion: review

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Reason for exclusion: review

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Reason for exclusion: descriptive only and case study example

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Reason for exclusion: measures cognitive, physical and psychosocial functioning. No measures related to wandering

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Reason for exclusion: not specific to wandering; no separate control group

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Reason for exclusion: descriptive study

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Reason for exclusion: no actual data on pacing given; no separate control group

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Reason for exclusion: no control group

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Reason for exclusion: subjective barriers

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Reason for exclusion: not wandering and no intervention

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Reason for exclusion: not specific to wandering

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Reason for exclusion: review

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Reason for exclusion: data on unsafe situations not wandering

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Reason for exclusion: review of drug therapies for agitation

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Reason for exclusion: measures sleep/wakefulness, activity. No data specific to wandering reported

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Reason for exclusion: case series – no control group

Gerdner LA. Effects of individualized versus classical 'relaxation' music on the frequency of agitation in elderly persons with Alzheimer's disease and related disorders. *Int Psychogeriatr* 2000;**12**(1):49–65.
Reason for exclusion: reports mean overall scores on CMAI but no data specific to wandering

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Reason for exclusion: measures overall agitation. Not specific to wandering.

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Reason for exclusion: case study

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Reason for exclusion: not specific enough to wandering; no control group

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Reason for exclusion: no actual data on pacing given; no separate control group

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Reason for exclusion: measures cognition, depression and ADL not wandering

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Reason for exclusion: review article

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Reason for exclusion: measures physical non-aggressive behaviour on CMAI but no data reported specific to wandering. No reply from authors.

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Reason for exclusion: case studies

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Reason for exclusion: review

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Reason for exclusion: not specific to wandering; no control group

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Reason for exclusion: doesn't give results specific to wandering

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Reason for exclusion: measures withdrawal, antisocial behaviour and ADL, not wandering

Hanley IG. The use of signposts and active training to modify ward disorientation in elderly patients. *J Behavior Ther Exp Psychiatry* 1981;**12**:241–7.
Reason for exclusion: not wandering + case study

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Reason for exclusion: measures ADL, verbal orientation, not wandering

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Reason for exclusion: no control group – not specific to wandering

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Reason for exclusion: no control group

Heard K. A functional analysis of wandering behavior in geriatric patients with Alzheimer's disease. *Diss Abstr Int Sect B: Sci Eng* 1998;**58**(7-B):3913.
Reason for exclusion: single subject design – no control group

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Reason for exclusion: sleep rather than wandering

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Reason for exclusion: commentary

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Reason for exclusion: review

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Reason for exclusion: reply from authors. Cannot locate data specific to wandering

Holmberg SK. Evaluation of a clinical intervention for wanderers on a geriatric nursing unit. *Arch Psychiatr Nurs* 1997;**11**(1):21–8.
Reason for exclusion: measures aggression. No data on unsafe wandering collected

Holmes C, Hopkins V, Hensford C, MacLaughlin V, Wilkinson D, Rosenvinge H. Lavender oil as a treatment for agitated behaviour in severe dementia: a placebo controlled study. *Int J Geriatr Psychiatry* 2002;**17**:305–8.
Reason for exclusion: reports overall agitation scores. No data specific to wandering

Holmes D, Teresi J, Weiner A, Monaco C, Ronch J, Vickers R. Impacts associated with special care units in long-term facilities. *Gerontologist* 1990;**30**:178–83.
Reason for exclusion: no data specific to wandering reported

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Reason for exclusion: same study as Kragt et al. (1997).

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Reason for exclusion: not specific to wandering – no control group

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Reason for exclusion: not specific to wandering

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Reason for exclusion: measures overall behaviour disorder. No actual data on wandering reported

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Reason for exclusion: reports physical non-agressive behaviour on CMAI. No actual data on pacing given. No response from authors

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Reason for exclusion: review

Hussian RA. Stimulus control in the modification of problematic behavior in elderly institutionalized patients. *Int J Behav Geriatr* 1982;**1**(1):33–42.
Reason for exclusion: only three participants; no control group

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Reason for exclusion: measures physical non-aggressive behaviour but no data reported. Reply from authors: did not collect data specific to wandering

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Reason for exclusion: measures positive and negative behaviours not wandering; no control group

Jeandel C. How to control wandering and yelling in the dementia patient. *Soins* 2004;**685**:44–5.
Reason for exclusion: review only

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Reason for exclusion: no control group

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Reason for exclusion: legal issues

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Reason for exclusion: no data on wandering/restlessness reported

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Reason for exclusion: no control group

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Reason for exclusion: not specific enough to wandering – no control group

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Reason for exclusion: case study

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Reason for exclusion: reports mean overall scores on CMAI. No data specific to wandering

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Reason for exclusion: one participant

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Reason for exclusion: review

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Reason for exclusion: outcomes not specific to wandering

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Reason for exclusion: description of legal cases

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Reason for exclusion: duplicated data

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Reason for exclusion: case study

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Reason for exclusion: reports mean behaviour change. No data specific to wandering

Libin A, Cohen-Mansfield J. Therapeutic robocat for nursing home residents with dementia: preliminary inquiry. *Am J Alzheimer's Dis Other Dement* 2004;**19**:111–16.
Reason for exclusion: measures physical agitation. No separate control group

Lord TR, Garnder JE. Effects of music on Alzheimer's patients. *Percept Mot Skills* 1993;**76**:451–5.
Reason for exclusion: measures mood and social interaction, not wandering

Lovell BB, Ancoli-Israel S, Gevirtz R. Effect of bright light treatment on agitated behavior in institutionalized elderly subjects. *Psychiatry Res* 1995;**57**:7–12.
Reason for exclusion: agitation only – no control group

Lund DA, Hill RD, Caserta MS, Wright SD. Video respite: an innovative resource for family, professional

caregivers, and persons with dementia. *Gerontologist* 1995;**35**:683–7.
Reason for exclusion: descriptive only

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Reason for exclusion: measures hours of sleep and mean behaviour change, not wandering

Maas M. Management of patients with Alzheimer's disease in long-term care facilities. *Nurs Clin North Am* 1988;**23**(1):57–68.
Reason for exclusion: descriptive only

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Reason for exclusion: no data specific to wandering (mood/behaviour)

Malaquin-Pavan E. Therapeutic benefit of touch-massage in the overall management of demented elderly [French]. *Recherche en Soins Infirmiers* 1997; **49**:11–66.
Reason for exclusion: only four patients; no control group

Marenzi R, Mari M, Girardello R. The value and limits of reality orientation therapy in nursing home patients. *Riabilitazione* 1992;**25**(1):33–8.
Reason for exclusion: does not measure wandering

Marshall M. *Dementia and technology: a discussion of the practical and ethical issues surrounding the use of technology in helping people with dementia*. London: Counsel and Care.
Reason for exclusion: not specific enough to wandering

Marx MS, Werner P. Cohen-Mansfield J. Agitation and touch in the nursing home. *Psychol Rep* 1989; **64**:1019–26.
Reason for exclusion: no intervention association between pacing and touch/distance from others

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Reason for exclusion: no control group

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Reason for exclusion: not wandering

McCabe BW, Baun MM, Speich D, Agrawal S. Resident dog in the Alzheimer's special care unit. *West J Nurs Res* 2002;**24**:684–96.
Reason for exclusion: no specific data to wandering; no control group

McCallion P, Toseland RW, Freeman K. An evaluation of a family visit education program. *J Am Geriatr Soc* 1999;**47**:203–14.
Reason for exclusion: reports physical non-aggressive agitation

on CMAI – no actual data on pacing given. No response from authors

McGilton KS, Rivera TM, Dawson P. Can we help persons with dementia find their way in a new environment? *Aging Ment Health* 2003;**7**:363–71.
Reason for exclusion: reports mean overall agitation scores. No data specific to wandering

McGrowder-Lin R. Bhatt A. A wanderer's lounge program for nursing home residents with Alzheimer's disease. *Gerontologist* 1988;**28**:607–9.
Reason for exclusion: no control group

Miller S, Vermeersch PE, Bohen K, Renbarger K, Kruep A, Sacre S. Audio presence intervention for decreasing agitation in people with dementia. *Geriatr Nurs* 2001;**22**(2):66–70.
Reason for exclusion: not specific to wandering; no control group

Mintzer JE, Lewis L, Pennypaker L, Simpson W, Backman D, Wohlreich G, *et al*. Behavioral intensive care unit (BICU): a new concept in the management of acute agitated behavior in elderly demented patients. *Gerontologist* 1993;**33**:801–6.
Reason for exclusion: descriptive only

Mintzer JE, Colenda C, Waid LR, Lewis L, Meeks A, Stuckey M, *et al*. Effectiveness of a continuum of care using brief and partial hospitalization for agitated dementia patients. *Psychiatr Serv* 1997;**48**:1435–9.
Reason for exclusion: reports physical non-aggressive behaviour on CMAI – no actual data on pacing given

Mintzer JE, Hoernig KS, Mirski DF. Treatment of agitation in patients with dementia. *Clin Geriatr Med* 1998;**14**(1):147–76.
Reason for exclusion: review

Mion LC, Frengley JD, Jakovcic CA, Marino JA. A further exploration of the use of physical restraints in hospitalized patients. *J Am Geriatr Soc* 1989;**37**:949–56.
Reason for exclusion: not specific to wandering

Mishima K, Okawa M, Hishikawa Y, Hozumi S, Hori H, Takahashi K. Morning bright light therapy for sleep and behavior disorders in elderly patients with dementia. *Acta Psychiatr Scand* 1994;**89**:1–7.
Reason for exclusion: wandering was measured but results not reported – no data specific to wandering

Mishima K, Hishikawa Y, Okawa M. Randomized, dim light controlled, crossover test of morning bright light therapy for rest–activity rhythm disorders in patients with vascular dementia and dementia of Alzheimer's type. *Chronobiol Int* 1998;**15**:647–54.
Reason for exclusion: measures activity levels. Data not specific enough to wandering

Monsour N, Robb SS. Wandering behavior in old age: a psychosocial study. *Social Work* 1982;**27**:411–15.
Reason for exclusion: no intervention

Morgan DG, Stewart NJ. High versus low density special care units: impact on the behaviour of elderly residents with dementia. *Can J Aging* 1998;**17**:143–65.

Reason for exclusion: reports composite score of disruptive behaviour. No data specific to wandering

Musallam K, Cirelli D, Cascio HE, Hemphill GL. Patient Electronic Monitoring System (PEMS). *Int J Technol Aging* 1991;**4**:107–13.
Reason for exclusion: descriptive study only

Namazi KH, Haynes SR. Sensory stimuli reminiscence for patients with Alzheimer's disease: relevance and implications. *Clin Gerontol* 1994;**14**(4):29–46.
Reason for exclusion: no data specific to wandering

Negley EN, Molla PM, Obenchain J. No exit: the effects of an electronic security system on confused patients. *J Gerontol Nurs* 1990;**16**(8):21–5.
Reason for exclusion: descriptive only – no control group

Neugroschl J. Agitation: how to manage behaviour disturbances in the older patient with dementia. *Geriatrics* 2002;**57**(4):33–42.
Reason for exclusion: review

Okawa M, Mishima K, Hishikawa Y, Hozumi S, Hori H, Takahashi K. Circadian rhythm disorders in sleep–waking and body temperature in elderly patients with dementia and their treatment. *Sleep* 1991;**14**:478–85.
Reason for exclusion: reports data on sleep–wake rhythm and temperature. No data on wandering

Okawa M, Mishima K, Hozumi S. Effects of environmental stimulation with bright light and transcranial electrostimulation on sleep and behavior disorders in elderly patients with dementia. In Iqbal K. *et al*. editors. *Alzheimer's Disease and Related Disorders*. Chichester: Wiley; 1999. pp. 757–62.
Reason for exclusion: reports overall behaviour disorder changes. No data on wandering

Okawa M, Mishima K, Hozumi S. Light treatment for sleep–wake disorders in elderly patients with dementia. In Holick MF, Jung EG, editors. *Proceedings of a Symposium: Basel, Switzerland*. Dordrecht: Kluwer; 1998.
Reason for exclusion: data not specific enough to wandering

Okawa M, Mishima K, Hishikawa Y, Hozumi S, Hori H. Sleep disorder in elderly patients with dementia and trials of new treatments – enforcement of social interaction and bright light therapy. In Kumar VM, Mallick HN, Nayar U, editors. *Sleep–wakefulnes*. New Delhi: Wiley Eastern; 1993. pp. 128–32.
Reason for exclusion: data not specific to wandering

Okawa M, Mishima K, Shirakawa S, Hishikawa Y, Hozumi S, Hori H. Sleep disorders in elderly patients with dementia and attempts of bright light therapy: in senile dementia of Alzheimer's type and multi-infarct dementia. In Hiroshige T, Honma K, editors. *Evolution of circadian clock*. Sapporo: Hokkaido University Press; 1994, pp. 313–22.
Reason for exclusion: data not specific to wandering

Olderog-Millard KA, Smith JM. The influence of group singing therapy on the behavior of Alzheimer's disease patients. *J Music Ther* 1989;**26**(2):58–70.
Reason for exclusion: no data on wandering; no separate control group

Opie J, Doyle C, O'Connor DW. Challenging behaviours in nursing home residents with dementia: a randomized controlled trial of multidisciplinary interventions. *Int J Geriatr Psychiatry* 2002;**17**:6–13.
Reason for exclusion: no actual data on pacing given; includes drug therapy as intervention

Peak JS, Cheston RIL. Using simulated presence therapy with people with dementia. *Aging Ment Health* 2002;**6**(1):77–81.
Reason for exclusion: case studies. Does not measure wandering

Pinkney L. Comparison of the Snoezelen environment and a music relaxation group on the mood and behaviour of patients with senile dementia. *Br J Occup Ther* 1997;**60**:209–12.
Reason for exclusion: not wandering – no control

Powell C, Mitchell-Pedersen L, Fingerote E, Edmund L. Freedom from restraint: consequences of reducing physical restraints in the management of the elderly. *Can Med Ass J* 1989;**141**:561–4.
Reason for exclusion: falls not wandering

Rabinovich BA. Cohen-Mansfield J. The impact of participation in structured recreational activities on the agitated behaviour. *Activities Adaptation Aging* 1992;**16**(4):89–98.
Reason for exclusion: pacing omitted from analysis

Rader J. A comprehensive staff approach to problem wandering. *Gerontologist* 1987;**27**:756–60.
Reason for exclusion: descriptive only

Rader J, Doan J, Schwab M. How to decrease wandering, a form of agenda behavior. *Geriatri Nurs* 1985;**6**:196–9.
Reason for exclusion: descriptive only

Rader J. Modifying the environment to decrease use of restraints. *J Gerontol Nurs* 1991;**17**(2):9–13.
Reason for exclusion: case study

Ragneskog H, Kihlgren M, Karlsson I, Norberg A. A dinner music for demented patients: analysis of video-recorded observations. *Clin Nurs Res* 1996;**5**:262–82.
Reason for exclusion: no separate control group

Ragneskog H, Asplund K, Kihlgren M, Norberg A. Individualized music played for agitated patients with dementia: analysis of video-recorded sessions. *Int J Nurs Pract* 2001;**7**:146–55.
Reason for exclusion: no control group – not specific to wandering

Ragneskog H, Bråne G, Karlsson I, Kihlgren M. Influence of dinner music on food intake and symptoms common in dementia. *Scand J Caring Sci* 1996;**10**(1):11–17.
Reason for exclusion: no separate control group

Ragneskog H, Kihlgren M. Music and other strategies to improve the care of agitated patients with dementia. *Scand J Caring Sci* 1997,**11**:176–82.
Reason for exclusion: not specific to wandering

Rantz MJ, McShane RE. Nursing-home staff perception of behavior disturbance and management of confused residents. *App Nurs Res* 1994;**7**:132–40.
Reason for exclusion: descriptive only

Reeve W, Ivison D. Use of environmental manipulation and classroom and modified informal reality orientation with institutionalized, confused elderly patients. *Age Ageing*, 1985;**14**:119–21.
Reason for exclusion: reports overall mean behaviour changes not wandering

Reid RL. Designing for late-stage dementia care. *Provider* 2000;**26**(5):40–43.
Reason for exclusion: descriptive only

Remington, R. Calming music and hand massage with agitated elderly. *Nurs Res* 2002,**51**:317–23.
Reason for exclusion: reports physical non-aggressive behaviour on the CMAI. Not specific to wandering

Rheaume YL, Manning BC, Harper DG, Volicer L. Effect of light therapy upon disturbed behaviors in Alzheimer patients. *Am J Alzheimer's Dis* 1998:**13**:291–95.
Reason for exclusion: case studies

Richeson NE. Effects of animal-assisted therapy on agitated behaviors and social interactions of older adults with dementia. *Am J Alzheimer's Dis Other Dement* 2003; **18**:353–8.
Reason for exclusion: not specific to wandering; no separate control group

Riegler J. Comparison of a reality orientation program for geriatric patients with and without music. *J Music Ther* 1980;**27**(1):26–33.
Reason for exclusion: does not measure wandering

Robb S. Exercise treatment for wandering behavior. [abstract]. *Gerontologist* 1985;**25**(Special Issue S1):136.
Reason for exclusion: no control group

Robb SS, Stegman CE, Wolanin MO. No research versus research with compromised results: a study of validation therapy. *Nurs Res* 1986;**35**:113–18.
Reason for exclusion: measures mental status, morale and social behaviour, not wandering

Robbins LJ, Boyko E, Lane J, Cooper D, Jahnigen DW. Binding the elderly: a prospective study of the use of mechanical restraints in an acute care hospital. *J Am Geriatr Soc* 1987;**35**:296.
Reason for exclusion: descriptive only

Ross R, Gwyther L, Kahn D. Treatment of agitation in older persons with dementia. *Home Health Care Consult* 1999;**6**(5):19–29.
Reason for exclusion: review

Rowe M, Alfred D. The effectiveness of slow-stroke massage in diffusing agitated behaviors in individuals with Alzheimer's disease. *J Gerontol Nurs* 1999; **25**(6):22–34.
Reason for exclusion: no separate control group

Sansom G. Comparing multisensory stimulation with (1) tactile stimulation (2) themed reminiscence. *J Dement Care* 2004;**10**(4):38.
Reason for exclusion: no control group. Did not measure wandering behaviour

Sansone P, Schmitt L. Providing tender touch massage to elderly nursing home residents: a demonstration project. *Geriatr Nurs* 2000;**21**:303–8.
Reason for exclusion: measures pain and anxiety, not wandering

Satlin A, Volicer L, Ross V, Herz L, Campbell S. Bright light treatment of behavioral and sleep disturbances in patients with Alzheimer's disease. *Am J Psychiatry* 1992; **149**:1028–32.
Reason for exclusion: no specific data for wandering, no control group

Shimizu K, Kawamura K, Yamamoto K. Location system for dementia wandering. In *Proceedings of the 22nd Annual EMBS International Conference*. Chicago.
Reason for exclusion: descriptive re: device

Smallwood J, Brown R, Coulter F. Irvine E, Copland C. Aromatherapy and behaviour disturbances in dementia: a randomized controlled trial. *Int J Geriatr Psychiatry* 2001;**16**:1010–13.
Reason for exclusion: reported data includes other items not specific to wandering behaviour

Snyder LH, Rupprecht P. Pyrek,J. Brekhus,S, Moss,T. Wandering. *Gerontologist* 1978;**18**:272–80.
Reason for exclusion: no intervention

Snyder M, Egan EC, Burns KR. Efficacy of hand massage in decreasing agitation behaviors associated with care activities in persons with dementia. *Geriatric Nurs* 1995;**16**(2):60–3.
Reason for exclusion: reports mean agitation scores not wandering

Snyder M, Egan EC, Burns, KR. Interventions for decreasing agitation behaviors in persons with dementia. *J Gerontol Nurs* 1995;**21**(7):34–40.
Reason for exclusion: reports mean behaviour scores, not specific to wandering

Spaull D, Leach C. An evaluation of the effects of sensory stimulation with people who have dementia. *Behav Cogn Psychother* 1998;**26**:77–86.
Reason for exclusion: case series design

Spector A, Orrell M, Davies S, Woods B. Can reality orientation be rehabilitated? Development and piloting of an evidence-based programme of cognition-based therapies for people with dementia. *Neuropsychol Rehabil* 2001;**11**:377–97.
Reason for exclusion: wandering residents excluded from study

Strasser DC, Hennessy CH. Geriatrics. Restraint of ambulatory nursing home residents with cognitive impairments. *Rehabil R&D Prog Rep* 1994;**30**:98–99.
Reason for exclusion: not wandering – descriptive only

Suhr J, Anderson S, Tranel D. Progressive muscle relaxation in the management of behavioural disturbance in Alzheimer's disease. *Neuropsychol Rehabil* 1999;**9**(1):31–44.
Reason for exclusion: reports mean overall behaviour changes not specific to wandering

Sullivan-Marx EM. Delirium and physical restraint in the hospitalized elderly. *IMAGE J Nurs Scholarsh* 1994; **26**:295–300.
Reason for exclusion: review

Sullivan-Marx EM. Psychological responses to physical restraint use in older adults. *J Psychosoc Nurs* 1995; **33**(6):20–5.
Reason for exclusion: discussion paper

Sweep MAJ. Technology for people with dementia: user requirements. Eindhoven: Institute for Gerontechnology, University of Technology; 1998.
Reason for exclusion: related to product design

Tabloski PA, McKinnon-Howe L, Remington R. Effects of calming music on the level of agitation in cognitively impaired nursing home residents. *Altern Med J* 1995; **2**(2):27–32.
Reason for exclusion: no control group. Measures general agitation only.

Taft LB, Matthiesen V, Farran CJ, McCann JJ, Knafl K. A. Supporting strengths and responding to agitation in dementia care: an exploratory study. *Am J Alzheimer's Dis* 1997;**12**:198–208.
Reason for exclusion: not specific to wandering

Takada T, Nakai K. Tsuda,M. Practical research of a new patient recognition system. *Jpn J Med Inf* 1998; **18** (Suppl):45–6.
Reason for exclusion: two case studies

Tariot PN. Treatment strategies for agitation and psychosis in dementia. *J Clin Psychiatry* 1996: **57** (Suppl 14):21–9.
Reason for exclusion: review

Tariska P. Diagnostics and treatment of agitation in patients with dementia. *Psychiatr Hung* 2000;**15**(1):86–95.
Reason for exclusion: review paper

Teri L, Logsdon RG, Weiner MF, Trimmer C, Thal L, Whall AL, *et al*. Treatment for agitation in dementia patients: A behavior management approach. *Psychother Theory Res Practi Train* 1998;**35**:436–43.
Reason for exclusion: case studies, descriptive only

Thorp, L, Middleton J, Russell, G, Stewart N. Bright light therapy for demented nursing home patients with behavioral disturbance. *Am J Alzheimer's Dis* 2000; **15**(1):18–26.
Reason for exclusion: not specific to wandering; no control group

Tinetti ME, Liu W-L, Ginter SF. Mechanical restraint use and fall-related injuries among residents of skilled nursing facilities. *Ann Intern Med* 1992;**116**:369–74.
Reason for exclusion: not wandering

Toseland RW, Diehl M, Freeman K, Manzanares T, Naleppa M, McCallion P. The impact of validation group therapy on nursing home residents with dementia. *J App Gerontol* 1997;**16**(1):31–50.
Reason for exclusion: reports physical non-aggressive behaviour on CMAI – no actual data on pacing given. No response from authors

Tourigny AW, Demitrack LB, Feldman R. Wandering behavior and long-term care: autonomy vs. security. *J Long Term Care Admin* 1989,**17**(4):23–4.
Reason for exclusion: no intervention

Tuokko H, MacCourt P, Heath Y. Home alone with dementia. *Aging Ment Health* 1999;**3**(1):21–7.
Reason for exclusion: descriptive only

van Diepen E, Baillon SF, Redman J, Rooke N, Spencer DA, Prettyman RA. A pilot study of the physiological and behavioural effects of Snoezelen in dementia. *Br J Occup Ther* 2002;65(2):61–6.
Reason for exclusion: reports mean overall agitation scores. No data specific to wandering

Wallace M, The sundown syndrome: will the specialized training of nurse's aides help elders with sundown syndrome? *Geriatr Nurs* 1994;**15**:164–6.
Reason for exclusion: no control group

Wallis GG, Baldwin M, Higginbotham P. Reality orientation therapy: a controlled trial. *Br J Med Psychol* 1983;**56**:271–7.
Reason for exclusion: reports overall behaviour change not wandering

Wareing L-A, Coleman PG, Baker R. Multisensory environments and older people with dementia. *Br J Therapy Rehabil* 1998;**5**:624–9.
Reason for exclusion: case study – not specific to wandering

Weinstein LB, Rowe M, Alfred D. The effectiveness of slow-stroke massage in diffusing agitated behaviors in individuals with Alzheimer's disease. *J Gerontol Nurs* 1999;**25**(5).
Reason for exclusion: letter only

Wells Y, Jorm AF. Evaluation of a special nursing home unit for dementia sufferers: a randomised controlled comparison with commuity care. *Aust N Z J Psychiatry* 1987;**21**:524–31.
Reason for exclusion: reports mean behaviour problems. Not specific to wandering

Werner P, Cohen-Mansfield J, Braun J, Marx MS. Physical restraints and agitation in nursing home residents. *Am Geriatr Soc* 1989;**37**:1122–6.
Reason for exclusion: restraints and pacing but on medication

Williams R, Reeve W. Ivison,D. Kavanagh D. Use of environmental manipulation and modified informal reality orientation with institutionalized, confused elderly subjects: a replication. *Age Ageing* 1987; **16**:315–18.
Reason for exclusion: does not measure wandering

Wimo A, Nelvig A, Nelvig J, Adolfsson R, Mattsson B, Sandman PO. Can changes in ward routines affect the severity of dementia? A controlled prospective study. *Int Psychogeriatr* 1993;**5**:169–80.
Reason for exclusion: not specific to wandering

Woods DL, Dimond M. The effect of therapeutic touch on agitated behavior and cortisol in persons with Alzheimer's disease. *Biol Res Nurs* 2002;**4**:104–14.
Reason for exclusion: no control group

Woods P, Ashley J. Simulated presence therapy: using selected memories to manage problem behaviors in Alzhimer's disease patients. *Geriatr Nurs* 1995; **16**(1):9–14.
Reason for exclusion: no control group. Not specific to wandering/no data

Wrigglesworth M. Time for a fair assessment of all the options. *J Dement Care* 1996;(Nov/Dec):14–15.
Reason for exclusion: written by Managing Director of tagging company – bias

Wright LK, Litaker M, Laraia MT, DeAndrade S. Continuum of care for Alzheimer's disease: a nurse education and counseling program. *Iss Ment Health Nurs* 2001;**22**:231–52.
Reason for exclusion: measures overall agitation not specific to wandering. No response from authors

Yamamoto H, Wakamatsu H. Effect of electronic safeguard system for senile dementia patients in its application at home. *Jpn J Med Electron Biol Eng* 1999; **37**:3–301.
Reason for exclusion: case study

Young SH, Muir-Nash J, Ninos M. Managing nocturnal wandering behavior. *J Gerontol Nurs* 1988;**14**(5):6–12.
Reason for exclusion: no actual data on wandering provided

Zeisel J, Silverstein NM, Hyde J, Levkoff S, Lawton MP, Holmes W. Environmental correlates to behavioral health outcomes in Alzheimer's special care units. *Gerontologist* 2003;**43**:697–711.
Reason for exclusion: Reply from authors: no data on wandering available

Appendix 6

Data abstraction forms

Systematic Review of Wandering in Dementia
Data Extraction Form

Data extracted by: _____   Date:_____

Inclusion criteria satisfied? (check protocol)

YES → complete form

NO   → do not complete form; record reason for exclusion below:

_____

A. PUBLICATION DETAILS

A1. First author, year, reference:

_____

_____

_____

A2. Country in which the study took place:

_____

A3. Publication status (please circle):

Published in peer reviewed journal / published in non peer reviewed journal / unpublished /
conference proceedings / thesis / other (please state below)

_____

B. STUDY DETAILS

B1. Area of intervention (check protocol; please circle):

Physical barrier / physical restraint / electronic device / behavioural intervention /
prevention or distraction therapy / alternative therapy / sensory therapy / environmental design

B2. Setting (please circle):

Home / day centre / hospital / residential home / nursing home

B3. Type of paper (please circle):

Empirical study	**GO TO C**	**PAGE 2**
Review or discussion of acceptability and/or ethics	**GO TO G**	**PAGE 16**

1

C. METHODS

C1. Research question / hypothesis stated:

	Page

C2. Sampling frame and strategy:

	Page

C3. Inclusion / exclusion criteria (e.g. age, gender, type of cognitive impairment, degree of cognitive impairment, behavioural symptoms):

	Page

C4. Detailed description of intervention (e.g. treatment, treatment provider, frequency, amount):

	Page

C5. Detailed description of comparison or control intervention:

	Page

C6. Study design (please choose from list in C7. If the study has a different design, please give details below):

	Page

C7. If study design is (please tick):

(i) Randomised controlled trial   [   ] → **GO TO D1**.   **PAGE 4**

(ii) Non-randomised controlled trial   [   ] → **GO TO D2.**   **PAGE 5**

(iii) Controlled before and after study   [   ] → **GO TO D3.**   **PAGE 6**

(iv) Cohort study   [   ] → **GO TO D4.**   **PAGE 7**

(v) Case control study   [   ] → **GO TO D5**.   **PAGE 8**

(vi) Economic evaluation:

     With modelling   [   ] → **GO TO D6.**   **PAGE 9**

     Without modelling   [   ] → **GO TO D6.**   **PAGE 9**

(vii) Qualitative (acceptability or ethical)   [   ] → **GO TO D7.**   **PAGE 10**

(viii) Other   [   ] → **GO TO E1.**   **PAGE 11**

D. FURTHER DETAILS AND QUALITY CRITERIA

D1. Randomised controlled trial:

	Page
a. Randomisation (adequate / unclear / inadequate):	
b. Individual or cluster randomisation:	
c. Concealment of allocation (adequate / unclear / inadequate):	
d. Primary outcomes and how measured:	
e. Secondary outcomes and how measured:	
f. When outcomes are measured:	
g. Blinding of outcome assessors (adequate / unclear / inadequate):	
h. Mean or median treatment duration (specify which):	
i. Mean or median duration of follow-up (specify which):	

D2. Non-randomised controlled trial:

	Page
a. How control group was chosen:	
b. Concealment (adequate / unclear / inadequate):	
c. Primary outcomes and how measured:	
d. Secondary outcomes and how measured:	
e. When outcomes are measured:	
f. Blinding of outcome assessors (adequate / unclear / inadequate):	
g. Mean or median treatment duration (specify which):	
h. Mean or median duration of follow-up (specify which):	

→ **NOW GO TO E1.   PAGE 11**

D3. Controlled before and after study:

	Page
a. Primary outcomes and how measured: b. Secondary outcomes and how measured: c. When outcomes are measured: d. Blinding of outcome assessors (adequate / unclear / inadequate): e. Duration of data collection before intervention: f. Duration of data collection after intervention: g. Any changes introduced during study period apart from intervention:	

D4. Cohort study:

	Page
a. Prospective or retrospective study:	
b. How cohort was defined (e.g. geographically, temporally):	
c. Primary outcomes and how measured:	
d. Secondary outcomes and how measured:	
e. When outcomes were measured:	
f. Blinding of outcome assessors (adequate / unclear / inadequate):	
g. Mean or median treatment duration (specify which):	
h. Mean or median duration of follow-up (specify which):	

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D5. Case control study:

	Page
a. Prospective or retrospective study:	
b. Matching of cases and controls (yes / no):	
c. If yes, what were they matched on (e.g. age, gender, MMSE score):	
d. Primary outcomes and how measured:	
e. Secondary outcomes and how measured:	
f. When outcomes were measured:	
g. Blinding of outcome assessors (adequate / unclear / inadequate):	
h. Mean or median treatment duration (specify which):	

D6. Economic evaluation (source of effectiveness data):

(i) Single study? YES   → <u>complete relevant section D 1-5 above</u>

         NO   → <u>go to D6 (ii)</u>

(ii) Review of previously published studies? YES   → <u>complete box below</u>

                NO → <u>go to D6 (iii)</u>

	Page
a. Study designs (criteria for inclusion in review):	
b. Sources searched (to identify primary studies):	
c. Quality criteria for studies (to assess validity):	
d. Quality methods for data extraction (sifting, selecting and reviewing papers):	
e. Number of studies included:	
f. Outcomes assessed (e.g. mortality, QoL):	
g. Method of combination (e.g. meta-analysis, narrative):	
h. Differences between studies (e.g. between participants, interventions etc):	
i. Results of the review:	

→ **NOW GO TO E2.   PAGE 11**

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(iii) Estimates of effectiveness based on opinion:

a. Methods used (e.g. consensus, expert opinion, author's assumptions):	Page
b. Estimates of effectiveness and key assumptions:	

D7. Qualitative study:

a. Perspectives included (e.g. person with dementia, proxy for person with dementia (please state), informal carers, other (please state):	Page
b. Methods of data collection (e.g. interview, focus group):	
c. What questions were asked:	
d. Were methods clearly described so as to allow for replication:	

E. ANALYSIS

E1. Efficacy studies:

	Page
a. Type of analysis:	
b. Was analysis by intention to treat (if a controlled trial design):	
c. Was there adjustment for clustering (if clustering applicable):	
d. Was there adjustment for confounders (if not randomised):	
e. Did the analysis allow for matching (if matching applicable):	

E2. Economic evaluation:

	Page
<u>Health benefits used in analysis</u>: a. Health benefit measure used:	
b. Type of model adopted (if applicable):	
c. Measure of valuation (if applicable):	
d. Whose values measured (if applicable):	
d. When valued (if applicable):	
e. How valued (if applicable):	

11

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	Page
<u>Costs included:</u> a. Direct or indirect costs included: b. Resource quantities reported separately: c. Cost items (hospital, patient/carer, health service etc): d. How costs were derived (based on actual data or modelling techniques): e. Incremental or average costs given: <u>Costs discounted:</u> a. Discount rates given if applicable: <u>Sensitivity analysis:</u> a. Was a sensitivity analysis of costs/benefits carried out: b. What methods were used: c. What parameters were tested:	

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E3. Qualitative study:

a. Type of analysis:	Page
b. Was analysis clearly described so as to allow for replication:	
c. Was analysis theoretically justified:	
d. Was analysis carried out by more than one researcher:	

→ **NOW GO TO F3.   PAGE 15**

F. RESULTS

F1. Efficacy studies:

	Intervention A	Intervention B (if applicable)	Control	Page
a. Number of subjects				
b. Age (mean, range):				
c. Male (%):				
d. Baseline MMSE or other test score, please specify (mean, range):				
e. Baseline comparability of treatment and control groups on age, gender or other, please specify (yes/no/unclear):				
f. No. of subjects assessed at each endpoint:				

	Intervention A	Intervention B (if applicable)	Control	Page
g. No. of withdrawals (%) and cause:				
h. Mean no. attempted exits per subject / no. of subjects assessed:				
i. Mean no. successful exits per subject / no. of subjects assessed:				
j. Mean no. and nature of accidents per subject / no. of subjects assessed:				
k. No. and cause of deaths / no. of subjects whose vital status was known:				
l. No. of subjects who attempted exit / no. of subjects assessed:				
m. No. of subjects with successful exit / no. of subjects assessed:				
n. No. of subjects who had an accident / no. subjects assessed:				
o. Mean quality of life score (SD) and no. of subjects assessed:				
p. Mean anxiety / distress score (SD) and no. of subjects assessed:				
q. Mean satisfaction score (SD) and no. of subjects assessed:				
r. Other (please state):				

F2. Economic evaluation:

	Page
a. Estimated benefits used in economic analysis: b. Cost results and discount rates: c. Costs and benefits combined (e.g. cost/life years gained): 	

→ **NOW GO TO G.**   **PAGE 16**

F3. Qualitative study:

	Page
a. Number of participants: b. Characteristics of participants: c. Main findings (describe fully): d. Was original evidence reported (e.g. quotes): e. Were negative cases or dissenting views reported: f. Were findings triangulated: 	

→ **NOW GO TO G.**   **PAGE 16**

G. DISCUSSION

G1. Were ethical issues discussed (if yes please describe main themes, whose perspectives were included and whether these were related to empirical evidence or opinion-based):

	Page

G2. Were acceptability issues discussed (if yes please describe main themes, whose perspectives were included and whether these were related to empirical evidence or opinion- based):

	Page

H. CONCLUSIONS

H1. What major limitations does the study have other than those noted above under quality?

H2. Any grey literature or additional references identified in the study to be followed up:

H3. Reviewer's notes:

Appendix 7

A framework for a Markov cost-effectiveness analysis model of wandering prevention strategies

Modelling is an analytical approach which can be used to evaluate the long-term cost-effectiveness of an intervention and to quantify uncertainty in cost-effectiveness issues. It makes a simplified representation of a real context, with its key factors and characteristics, within a framework using clinical effectiveness and cost-effectiveness data and information about the natural progression of the disease.[129–131]

Methods

A Markov epidemiological model allows a hypothetical cohort of people to be followed over a period. This period is divided into cycles which can correspond to a variety of factors, for example, what is known about patients' behaviour, the periods for which reliable data are available or the period related to the treatment regime. The model requires the definition of a finite set of 'mutually exclusive' clinical states or outcomes in which a patient can be found and the natural progression of patients' behaviour is represented by transitions from one state to another.[132,133] At each point in time when a transition occurs, the patient has an option of moving to one of several new states and the probabilities of moving to these states need to be defined: ideally, these *transition probabilities* should be estimated from national data or large cohort studies. The effects of an intervention and its comparator can be built into the model, hence estimates of the long-term costs and benefits of interventions can be made. For internal validity, the population providing estimates of the effect of an intervention should have similar socio-demographic and prognostic characteristics to that providing estimates of transition probabilities. A parallel costing study must be carried out to accompany the model to estimate the costs attributable to each pathway.

Patterns of cost should be estimated over an appropriate survival period. Costs concern the intervention adopted, its implementation (start-up costs and follow-up costs) and the subsequent use of resources. In principle, costs should include those related to the use of equipment and services, supervision needed, advice/training to carers, use of medications in relation to the intervention adopted, any use of services due to the treatment of collateral effects caused by the intervention and any change in use of services due to modifications in wandering behaviour (e.g. accident-related hospital admissions avoided). In practice, not all those cost items may be required and only a selection of items relevant to the specific interventions under investigation may need to be included in the cost-effectiveness analysis.

Development of the framework for the model

Wandering can have beneficial effects for people with dementia and it would not be cost-effective to prevent safe wandering. However, it is important to measure the negative consequences of wandering. There is a link between wandering and accidents, in particular, those due to exits from care areas. For example, in one paper reviewing people with dementia who had gone missing (463 reported episodes), the following injuries were reported: five head injuries, four cases of dehydration, 20 skin injuries and one injury from exposure to cold.[134] It has also been reported that wandering interferes with the successful administration of treatments and participation in daily activities and programmes.[48] Wandering behaviour also affects staff workload, in terms of time and effort to address the problem.[48] This can also have an impact on staff morale and increase replacement rates.[30] Potentially, staff may try to avoid the patients, and this yields a decrease in medical monitoring and social interactions.[48] However, based on the ethos and objectives of the study, that is to determine the effectiveness and cost-effectiveness of interventions to prevent wandering, and the availability of data and feasibility considerations, the framework for the model is restricted to the analysis of the risks to the patients' health and related costs.

The economic evaluation should ideally have addressed the perspectives of patients, carers and service providers and investigated the cost-
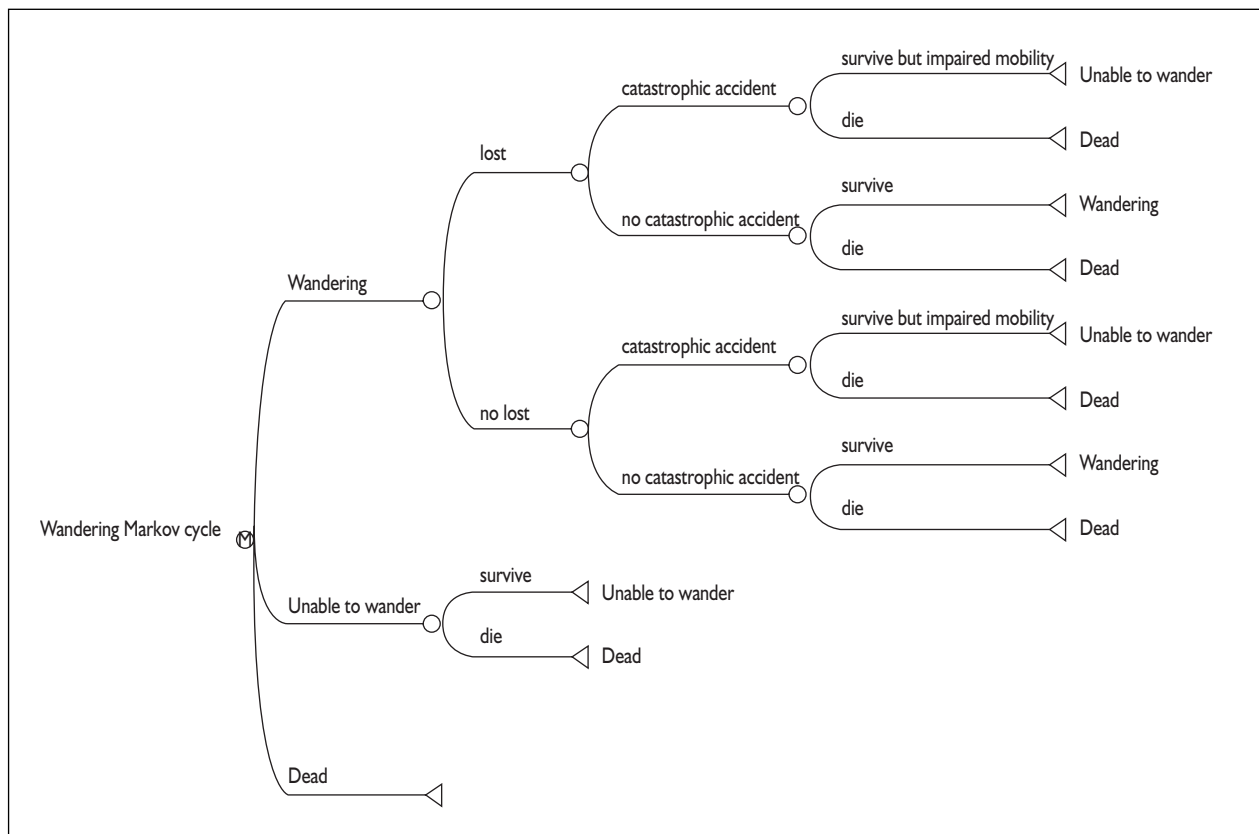
FIGURE 4 *Structure for an epidemiological model of wandering for a cohort of chronic wanderers*

effectiveness of the interventions in any care environment, either home, or hospital or institution. However, the clinical studies included in the clinical effectiveness review were specific to day-care or long-term institutional care,[43–50,52,53] and therefore the economic assessment is confined to this setting.

Where possible, the additional epidemiological data required should be extracted from large cohort studies. One such study which could potentially provide relevant data is the Medical Research Council Cognitive Function and Ageing Study (MRC CFAS) dataset. MRC CFAS is a large-scale multi-centre population-based epidemiological study of ageing. The project database contains longitudinal information on the health states of the study cohort, focusing on cognitive and physical decline in later years (http://www.cfas.medschl.cam.ac.uk). Data collected included whether the elderly person was prone to wandering and, if so, whether the wandering behaviour presented problems for the carer. However permission is required before the data can be used for external purposes. Although MRC CFAS might provide estimates of morbidity for the people who wander and those who do not, it did not provide much of the additional

epidemiological data required to estimate transition probabilities for our framework. As the framework was for illustrative purposes only, examples of the type and source of epidemiological and cost data which could be incorporated are provided.

The key elements of the epidemiological model are described below alongside the assumptions we made. The model was created using TreeAge Pro 2005 (Healthcare module).

States and transitions (see *Figure 4*)

We identified a set of mutually exclusive states for a hypothetical cohort of patients affected by chronic wandering behaviour:

- Wandering.
- Unable to wander, that is, individuals who are bedridden or so frail that they are unable to walk or move by wheelchair without assistance.[135]
- Dead.

Subjects who wander may or may not get lost. In either case, they may or may not have a catastrophic accident. Again, in either case, they may survive or die. We defined a catastrophic accident as a serious

injury or event which caused an accelerated decline in the general health of the patient, leaving them permanently unable to wander.

The wandering cycle

Several studies have described a variety of wandering activity among individuals.

Hope and colleagues[136] reported that in a typical day, apart from meal times, people with dementia and marked hyperactivity walked constantly while awake, sitting on average no more than 15 minutes at a time. Some people would not even sit for meals, and would walk without interruption, unless wandering was prevented.

Snyder and colleagues[11] reported that people with dementia who wandered moved about during 33% of 18 10-minute observations.

Cohen-Mansfield and colleagues[15] reported that, during 679 3-minute observation periods for six people who wandered, pacing was seen 55% of the time and continued throughout the entire period in 77% of all observations. Among 156 residents who paced, 38 did so less than daily, 72 paced several times in a day and 48 paced at least hourly.

Rossby and colleagues[137] reported that, even when seated in a Geri-Chair, residents were able to move themselves from one place to another, although the amount of wandering decreased considerably.

Algase and colleagues[138] reported that, for a group of 25 residents with dementia who were ambulant, the proportion of people who wandered increased as the day progressed: 23% during the night shift, 39% during the day and approximately 57% during the evening. Peak times for frequency of wandering episodes were 5 and 6 p.m. and for minutes of wandering were 9.00 a.m. and 6.00 p.m. hours. Random walking (as opposed to lapping or pacing) had a prevalence of 77%.

Martino-Salzman and colleagues[7] reported that, in an observational study of 40 residents, the frequency of wandering peaked around 7 p.m. Lapping was the wandering pattern in 90% of the cases and random walking represented 5% of wandering.

Matteson and Linton[139] reported that, from a total of 1764 observations of 49 ambulatory nursing home residents with dementia, 24 pacing episodes were observed during the day shift, 16 during the evening shift and 12 during the night shift. However, the investigators focused on pacing only, which is one subcategory of wandering.

Algase and colleagues[138,140–142] described wandering as a rhythmic ambulation yielding cycles which have two phases, a locomoting phase when the subject ambulates, and a non-locomoting phase, when the subject sits, lies or stands. In an observational study of 25 residents in a long-term care institution, mean age 85 years with a distribution of cognitive impairment from mild to severe, on average 19.7 wandering cycles were observed during a 24-hour observation period (SD 27.5, range 0–120), corresponding to a cycle length of 73 minutes (range 12 minutes to 1 day). On average, the locomoting phases lasted 43 minutes (SD 53; range 0–199). Frequency and total duration of wandering were moderately stable over a 3-day period.[138]

Because of the reported diurnal variation in wandering behaviour, the cycle assumed for the Markov model was 24 hours.

Definitions of probabilities

We assumed that the cohort included 1000 people with dementia and that initially all were in the wandering state.

Transition probabilities and rates

A transition probability refers to the probability of transition from one state to another during a cycle of time t.

Transition probabilities from wandering to experiencing the first major event were adjusted to the cycle length; subsequent transitions were not.

A *rate* refers to the probability of transition from one state to another at a specific point in time.

The transition probability relevant to a cycle of length c, can be estimated from the transition probability for a different time period, t, using the following equation:[132]

$$P_c = 1 - (1 - P_t)^{c/t} \qquad (1)$$

where P_c is the transition probability over the cycle of length c and p_t is the transition probability over time period t.

If the literature provides rates and not transition probabilities, the rates can be converted into probabilities using the equation[133]

$$p_t = 1 - e^{-rt} \qquad (2)$$

where r is the rate at which an event occurs.

Estimation of transition probabilities

We searched the literature for data on either *transition probabilities* or rates. Generally, when more than one probability value is identified, the use of a weighted-average based on the source sample size is recommended as larger population studies should be given more weight than smaller studies. The range of the reported values can be used in the sensitivity analysis.

The epidemiological model data, their sources and the derived transition probabilities are discussed below.

Getting lost following wandering

McShane and colleagues[143] conducted a longitudinal study on a sample of 104 subjects with dementia. Over a period of 5 years of follow-up, 43 subjects became lost. These data were used as a baseline rate in our model (since only a few got lost more than once, we assumed all residents got lost only once). Using equation (1), we estimated the transition probability of getting lost in a Markov cycle of length 73 minutes to be 1.48×10^{-5}.

Other transition probabilities and/or rates may be available, and could be used in the sensitivity analysis. For example, the same study reported that over 5 years, 25% of a sample of 53 wanderers were admitted into institutional care.[143] Less conservative estimates have been provided but these are for people with dementia living in the community; for example, it has been reported that less than 4% of people who wander away from home are able to return unassisted.[134]

Catastrophic accidents in people with dementia who get lost

From our literature search, the only evidence related to injuries following elopement was from community-based studies.[135,141–145] Therefore, it was not relevant for inclusion in the framework of the model but it is provided for information.

Silverstein and colleagues[144,145] reported that, out of a sample of 463 caregivers of people living in the community who wandered and got lost, 70% reported a serious consequence/injury as a result of their wandering.

Rowe and Golver[134] provided a summary of the injuries sustained by a sample of missing individuals: in 493 reported episodes of people with dementia who went missing, there were five head injuries, 20 skin injuries, four cases of dehydration and one injury from exposure to cold. There was no mention of fractures, although the skin and head injuries may have been caused by falls.

Catastrophic accidents in people with dementia who do not get lost

This group of people included individuals who eloped but managed to find their way back to their place of residence (4% of all elopements);[146] therefore, it is plausible to assume that the probability of catastrophic accidents is nil.

Attempts at elopement are not infrequent: it has been reported that over a 15-hour period, a population of 28 wanderers attempted to leave the unit in which they were residents 457 times.[147] However, this study does not provide any information about the probability of catastrophic accident in people with dementia who do not get lost.

From the literature reviewed, it remains unclear whether falls are related to wandering; one observational study found that they were not typical. In a sample of 193 individuals, 27% of the subjects reported falls since the onset of their dementia symptoms, regardless of frequency of wandering.[148] Since the onset of dementia, people who wandered were no more likely to have fallen than subjects who did not wander. These findings are consistent with the common assumption in routine practice that subjects who wander generally enjoy better physical well-being and are able to maintain a balanced gait. In fact, wandering and escape behaviour have been found to be related to lower physical workload for staff.[149] However, we were unable to identify any quantitative information about transition probabilities relevant to the model.

In an observational longitudinal study of 126 people with Alzheimer's disease, the investigators found that 10 (8%) had a history of a combination of wandering and falls over 5.4 years.[150] However, this study provided no evidence for other forms of dementia. It is also unclear whether the number of falls related to people who did or did not get lost, so we were unable to use these data in the model.

Survival in people with dementia who got lost and had a catastrophic accident

In a retrospective study of 42 people with Alzheimer's disease who got lost, no fatalities were reported for patients found within 24 hours, but 46% of those not found within 24 hours were dead

when located.[151] However, this paper did not provide any data either on the probability of a catastrophic accident following getting lost or on the probability of death following a catastrophic accident.

Survival in people with dementia who got lost, but did not have a catastrophic accident
We were unable to find any relevant data in the literature and we therefore assumed that the probability of death following getting lost was infinitesimally low in people who did not experience a catastrophic accident.

Survival in patients who did not get lost, but had a catastrophic accident
One study reported that in a sample of 126 outpatients who were followed for at least 6 years, the combination of wandering and falling reduced mean survival by more than 3 years.[36] However, we were unable to use any data from this study, first because it did not report survival rates and second because it is unclear whether the reduction in survival was confined to wandering patients who did not get lost. It may be reasonable to assume that survival in patients who had a catastrophic accident is similar whether they did or did not get lost.

Survival in patients who did not get lost and did not have a catastrophic accident
We were unable to find any relevant data in the literature and we therefore assumed that the probability of death following getting lost was infinitesimally low in people who did not experience a catastrophic accident.

Survival in patients unable to wander
This group of patients is so frail that they are unable to wander and are likely to be bedridden or confined to a chair. It may be possible to extract relevant data from the MRC CFAS datasets if further developing the model.

In summary, the only transition probability for which we found available data in the literature was for people with dementia who got lost following wandering.

State rewards
These are values of the outcome measures associated with a particular health state (e.g. costs or life-years gained). An annual discount rate of 5% is usually applied to rewards. To estimate the total rewards, the percentage of the cohort in a specific state during a cycle is multiplied by the rewards associated with that state.

Termination condition
For the current population (elderly people with dementia), it is recommended that the model is run for a number of cycles which corresponds to the expected lifespan of the participants.

Covariates
Estimates of prevalence rates of wandering in relation to the level of cognitive impairment have been reported in the literature: 12–18% for mild, 22–24% for moderate and 38–50% for severe impairment.[152,153] About 53% of people with MMSE ≤ 10 had never wandered and 20% with MMSE ≥ 24 had wandered.[148]

No association independent of cognitive impairment has been found between gender, age, education, race or ethnicity and wandering.[15,135,148,154–158]

In a longitudinal study by Hope and colleagues[136] which followed 86 people with dementia in the community over a 10-year period, changes in wandering behaviour were not related to gender, age or time since the onset of dementia. However, the onset and duration of different types of wandering were found to be related to cognitive levels. For example, Hope and colleagues reported that although subjects walk aimlessly until their MMSE is equal to 1, attempts to leave home cease when the MMSE reaches 5. Random and lapping patterns of wandering increased as a percentage of overall ambulation as cognitive function declined, while the pacing pattern remains stable through all levels of impairment.[7]

Also Algase and colleagues[138] reported that severely impaired patients ambulate more. However, it has been highlighted that although wandering behaviour (as other behavioural symptoms) becomes more common as cognitive impairment increases, the relationship is not linear but can be represented by a concave function. In an observational study of 120 outpatients affected by cognitive impairment, the percentage of subjects presenting with wandering behaviour reached a peak (50%) when the stage on the Global Deterioration Scale was six (range of stages two to seven). At this stage, the incidence of the symptom differed significantly with respect to normal aged controls. At stage seven (very severe cognitive impairment), the percentage of wandering subjects was 18%, and the frequency of occurrence did not differ significantly from normal-aged controls.[159]

Therefore, it would be important to include level of cognitive impairment as a covariate, if relevant data of adequate quality were available.

The categories of costs of services for inclusion in the model

Cost rewards for inclusion in the model can be estimated by making use of a multi-attribute cost function. The categories of costs of services relate to the search for missing patients, the cure of cases who suffered catastrophic accidents and the long-term care in institutions of patients with or without impaired mobility.

The searching costs of missing patients

From a societal perspective, the resources involved in instances of elopement and missing individuals are likely to go beyond the NHS budget. In the USA, over half of the individuals lost in the community were assisted by the police to return to their place of residence.[145] More conservative data have been provided, with the police involved in 33% of the cases of missing people who wander.[160] These cases are likely to include individuals who have been able to walk longer distances and/or have been missing for several hours; although it should be noted that individual carers will have different levels of tolerating risk. In most cases, people with dementia who wandered from their home or other establishment are either found by neighbours or reported to the police by members of the public who are concerned by either the person's state of dress or their unusual behaviour. Cost data would be required in relation to the search of missing persons in terms of nature and number of public services involved.

Treatment of patients who suffered catastrophic accidents

The literature reported a low frequency of catastrophic accidents due to elopement, including head and skin injuries, dehydration and hypothermia, with skin injuries the most common.[134] No fractures were reported in this study, and it remains unclear whether wandering is related to the risk of falls/bone fractures. It would be important to establish the prevalence of fractures, since the costs of their treatment tend to be higher than those of other injuries. However, good information on this area would appear to be limited (Shaw F Royal Victoria Infirmary, Newcastle Upon Tyne, UK, personal communication, 2004). In a study of 240 people with dementia in nursing homes, it was reported

that (i) 1343 falls occurred during an observation period of 329 person-years, that is, 4.1 falls per person per year, and (ii) 33 falls (2%) resulted in fractures.[161] Predictors to identify nursing home residents at risk of falling have been attempted.[161,162] These include a history of wandering and/or previous falls, severe dementia, physical handicap and male gender.[161,162]

The estimation of unit costs for the treatment of these injuries is provided by the Department of Health.[163] In this respect, the model would include costs to the hospital (emergency) services only, under the assumption that most accidents in people with dementia are seen at the Accident and Emergency Department and that primary care services would be less likely to be involved.

Long-term care in institutions of people with dementia with or without impaired mobility

In the previous section, the difficulties of estimating the extra costs of care caused by wandering behaviour, either for people living in the community or in long-term care, have been highlighted. The framework we have developed is focused on institutional settings, and contrasting results on additional costs of care have been provided.

For the purpose of the model, it could be assumed that in the absence of the adoption of specific wandering prevention interventions, the overall costs of care for people who wander are similar to the costs of care of patients with dementia who do not wander. As mentioned previously, the literature on the costs of formal dementia care provides contrasting results, and most of the studies are not specific to the system in the UK or contain dated information.

Given the limited usefulness of the cost information provided in the literature, a number of *ad hoc* sources should be explored in order to gather the necessary cost data inputs for the model. Observational studies based on longitudinal datasets such as the MRC CFAS[164] surveys estimate the costs under usual care, by relating the use of services to levels of cognitive impairment and wandering behaviour. Estimates of costs of care in residential and nursing homes are available in the report on unit costs of health and social care prepared by the University of Kent at Canterbury.[165] A survey among local long-term care facilities could also be provided, in particular to find out the additional costs posed by the care of patients with impaired mobility.

Selection of intervention study for the application of the framework

In selecting a clinical study for the application of the framework, we recommend that the study should be of good quality and satisfy the following criteria.

The study found that the intervention was clinically effective.

The study uses of measures of outcomes from which it is possible to derive wandering-related probabilities.

Some studies used more than one measure of outcomes, and obtained contrasting results across different measures of outcomes. Under these circumstances, it was impossible to derive final conclusions on the effectiveness of the intervention. However, for the purpose of the economic evaluation only those measures of outcomes which can be translated into a wandering-related probability suitable for inclusion in the model are required.

Enough information on the use of resources or costs for the delivery of the intervention has been provided either in the trial publication itself, or in the related bibliography.

None of the ten studies included in the clinical effectiveness reviewed[43–50,52,53] fulfilled all of these criteria and so it was inappropriate to apply the framework.

Swanson and colleagues[49] found that standard care in an integrated residential unit (control) was more effective than the care provided in a special care unit (intervention). Initially, the study by Ingersoll-Dayton and colleagues[53] found that the individualised behaviour management programme yielded a more favourable outcome to the control group in terms of frequency of wandering, although over time an improvement was observed in both the experimental and control groups. Moreover, this study lacked information both on the quantities of resources deployed and on the types of interventions undertaken. Mitchell[52] found no difference between essential oils and control oils. McNamara and Kempenaar[45] found no difference in outcomes following a multi-sensory environment or tactile stimulation, as did two other individual studies on multi-sensory environment,[43,44] although a meta-analysis of the two studies[43,44] did prove effectiveness (*Figure 3*). Groene[48] found music therapy was non-significantly more effective than the control intervention on one measure of wandering, but significantly less effective on another.

Frisoni and colleagues[50] used the NPI scale to measure the effectiveness of special care units. However, it is not possible to derive model probabilities from this scale. The same measure of outcomes was used by Ballard and colleagues[46] to measure the effectiveness of essential oils. Also Landi and colleagues[47] who assessed the effectiveness of a moderate-intensity exercise programme, and Baker and colleagues,[43,44] who compared multi-sensory environment with one-to-one activity sessions, made use of outcome measures from which no transition probabilities could be derived. In addition, the paper by Landi and colleagues did not contain any information on the costs or resources used to implement the intervention.

Appendix 8
Coding framework from analysis and ethical and acceptability papers

1 Principles/values
  1.1 Societal/legal
- Civil liberties
- Reduction/prevention of harm
- Human rights
- Freedom/liberty
- De-humanising
- 'Best interests'
- Political (+ public opinion/engagement)
- Social control/secrecy
- Paternalism
- Risk-free society

  1.2 Person centred/individual
- Autonomy/independence
- Respect
- Vulnerability
- Dignity
- Privacy
- Security
- Comfort

2 Risk perception
  2.1 Legal/litigation
  2.2 Potential/hypothetical vs actual/real
  2.3 Safety: prevention/reduction of harm
  2.4 Seriousness/severity of risk

3 Carer's perspectives
  3.1 Tolerance of risk
  3.2 Strategies
  3.3 Relationship with person with dementia
  3.4 Reassurance (anxiety)

4 Person with dementia: user experience
  4.1 Negative connotations of intervention/stigma
  4.2 Criminal connotations
  4.3 Surveillance
  4.4 Tolerance of/compliance with the intervention
  4.5 Choice

5 Intervention/technology
  5.1 Practical difficulties using intervention
  5.2 Appropriateness
  5.3 Limits of intervention
  5.4 Training of users
  5.5 Evidence
  5.6 Utility: usefulness and acceptability
  5.7 Expectations of intervention

6 Consequences of intervention/technology
  6.1 Financial/staffing
  6.2 Replacement of contact
  6.3 Long-term/institutional
  6.4 Side-effects, care behavioural effects, mortality, morbidity
  6.5 False sense of security
  6.6 Benefits of intervention to staff
  6.7 Benefits of intervention to patient
  6.8 Quality of life (effects on)
  6.9 Consequences for professional identity

7 Decision-making
  7.1 Timing of intervention/trajectory/crisis point
  7.2 Balance of risk (e.g. judgements (safety + vulnerability)
  7.3 Capacity to consent to use the intervention/guardianship
  7.4 Control of decision-making process.
  7.5 Justification for professional's decision-making
- autonomy
- beneficence/doing good/doing what's best
- non-maleficence/avoiding harm
- justice/fairness (with respect to resources)
- rights/liberties/freedom/privacy/dignity
- duties and obligations
- consequences (e.g. safety)
- virtues (being truthful/honest; practical wisdom)
- guidelines

  7.6 Justification for carer's decision-making (including consequences of doing/not doing)

9 Overarching theme: conflicts/tensions
  9.1 Principles vs practical solutions
  9.2 Preventing vs promoting wandering/behaviour
  9.3 Social vs individual
  9.4 Risk perception vs perceived benefits
  9.5 Roles and responsibilities
  9.6 Purpose of restraint
  9.7 Contrasting perspectives

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Appendix 9
Estimation of standard deviation of measures of wandering

Landi and colleagues 2004[47]

We estimated that Landi and colleagues report a mean difference between intervention and control in wandering at end of follow-up of 22 (see Figure 1 in their paper). It is unclear whether this mean difference was based on a measure of wandering measured on a continuous scale or on a count of the number of episodes of wandering. We assumed the former.

Landi and colleagues do not report how many participants were assigned to each group, so we assumed that randomisation resulted in equal numbers (15) in the intervention and control groups.

Landi and colleagues report (page 237) that "patients in the treatment group showed a statistically significant reduction in behavior problems, such as wandering". It is unclear what level of statistical significance was used, but we assumed $p = 0.001$. If we assume that this p-value was derived from a two-sample t-test, then the appropriate equation to estimate the SD of the measure of wandering in each arm is (see Sections 9.6.1–9.6.2, pages 192–4, in Altman[166]):

$$ SD = \frac{\Delta T}{t(p,df)} \frac{1}{\sqrt{\frac{1}{N_t} + \frac{1}{N_c}}} $$

where $\Delta T = 22$ is the magnitude of the treatment effect, $N_t = 15$ is the number of participants in the intervention group, $N_c = 15$ is the number of participants in the control group and is the t-value corresponding to $p = 0.001$ and $N_t + N_c - 2$ degrees of freedom (*df*).

If we had assumed a less extreme significance, such as $p = 0.05$, the estimated SD of the treatment effect would have been larger (e.g. 29.4).

Swanson and colleagues 1993[49]

Swanson and colleagues report (page 296) that "the behavior [wandering] only occurred four

times in this group during the posttest period. Wandering occurred least among the control subjects, with reports of … only two incidents during the posttest period". It is unclear whether these occurrences were all in different participants or whether they include several episodes of wandering by individual participants. We assumed the former. It is then reasonable to assume that the occurrences follow a Poisson distribution (see Section 4.8, page 66, in Altman[166]), so the SD of the measure of wandering in each arm is the square root of the number of occurrences of wandering, i.e. SD = 2 and 1.4 in the intervention and control arms, respectively.

Ingersoll-Dayton and colleagues 1999[53]

Ingersoll-Dayton and colleagues report that the F-statistics for the main effects of groups (experimental and control) from repeated measures analysis of variance are $F(1,19) = 0.14$, 0.47, 1.11 for frequency, severity and mastery respectively, (see *Table 2*, page 58 in their paper).

Ingersoll-Dayton and colleagues do not report how many participants were assigned to each group, so we assumed that randomisation resulted in equal numbers (10) in the intervention and control groups, although this cannot be exactly correct as the total number of participants was 21.

Since the F-statistic reported in analysis of variance is (see Section 9, pages 205–17, in Altman[166]):

$$ F = \frac{\text{between-group sum of squares}}{\text{within-group sum of squares}} $$

we have

$$ \sigma^2 = \text{Within-group sum of squares} = \frac{F}{\text{between group sum of squares}} $$

The between-group sum of squares can be calculated from the means of main effects which

Ingersoll-Dayton and colleagues present in *Table 3*, page 58 in their paper.

The SD of the measure of wandering in each arm is:

$$\text{SD} = \sqrt{\frac{\sigma^2}{N}}$$

where σ^2 is the within-group sum of squares and $N - k = 21 - 2 = 19$ is the number of degrees of freedom. Hence we have

	Frequency	Severity	Mastery
Intervention	1.65	0.04	1.14
Control	1.38	0.72	0.60
Overall mean	1.52	0.88	0.87
Between-group sum of squares	0.365	0.512	1.458
F	0.14	0.47	1.11
Within-group sum of square (19 df)	0.384	0.918	0.761
Within-group mean square	0.0202	0.0483	0.0401
SD	0.14	0.22	0.20

These estimated SDs are almost certainly too narrow as they ignore the repeated measures nature of the analysis of variance performed by Ingersoll-Dayton and colleagues.

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