

1 Appendix L: Research recommendations

L.1.2 Dementia diagnosis (amyloid PET imaging)

Research recommendation 1	Does amyloid PET imaging provide additional diagnostic value, and is it cost effective, for the diagnosis of Alzheimer's disease and other dementias when compared with standard diagnostic procedures?
Population	People (aged 40 years and over) with a suspected diagnosis of dementia, who have already undergone initial assessment in a specialist dementia diagnostic service
Index Test	Amyloid PET imaging
Reference Test(s)	<ul style="list-style-type: none"> • Diagnosis of dementia according to established clinical criteria • Diagnosis of dementia based on neuropathology
Outcomes	<ul style="list-style-type: none"> • Sensitivity and specificity • Positive and negative likelihood ratios • Resource use and costs
Study design	Diagnostic cross-sectional studies (case-control studies should be avoided)

3

Potential criterion	Explanation
Importance to patients, service users or the population	Amyloid imaging could prove useful in the diagnosis of individuals with dementia who lack a formal dementia subtype diagnosis after initial assessment in specialist care. The diagnosis of a correct dementia subtype can improve people's future care by allowing the support provided to be tailored to their specific needs. It is hypothesised that amyloid imaging could provide additional diagnostic value, over and above that of other imaging and diagnostic tests, and therefore improve the accuracy of dementia diagnostic pathways.
Relevance to NICE guidance	Moderate priority: it was not possible to make a recommendation on this issue due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	There was only limited evidence available around the accuracy and cost-effectiveness of amyloid imaging despite licensed products now being available.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the difficulty of diagnosing dementia in people with learning disabilities).
Feasibility	There is a large enough population of people presenting with suspected dementia that diagnostic accuracy studies in this area should be feasible.

4

L.2₁ Assessing for dementia after delirium

Research recommendation 2	In people with treated delirium who no longer meet the DSM-5 criteria, but who have persistent cognitive deficits, when is the most appropriate time to carry out an assessment for dementia?
Population	People (aged 40 years and over) with cognitive impairment and resolved delirium
Intervention	Repeated assessments for dementia following the resolution of delirium
Outcomes	<ul style="list-style-type: none"> • Incidence of dementia detected at each time point • Time at which cognitive scores stabilise
Study design	Repeated measures prospective cohort study (whilst this question could be addressed by RCTs of different assessment times, as no intervention would be offered to people in whom dementia is not identified, a repeated measures cohort study should provide the same data in an easier to undertake study)

2

Potential criterion	Explanation
Importance to patients, service users or the population	Delirium may mask other cognitive deficits and it is therefore important that people who have been diagnosed with delirium are assessed for dementia once the acute delirium has been resolved. Assessing too early may mean the residual effects of the delirium lead to false positives, whilst assessing too late may either lead to delays in identification, or that contact may be lost with them after their acute delirium symptoms have resolved, and the assessment therefore not undertaken.
Relevance to NICE guidance	Moderate priority: it was not possible to make a recommendation on this issue due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	There is uncertainty surrounding the best time to administer tests to detect dementia in people whose acute delirium has resolved.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the difficulty of diagnosing dementia in people with learning disabilities).
Feasibility	There is a large enough population of people presenting with delirium that a prospective cohort study in this area should be feasible.

3

L.3₁ Case finding

Research recommendation 3	What is the effectiveness of structured case finding (including a subsequent intervention for people identified as having dementia) in people at high risk of dementia, following up both people identified as having or not having dementia?
Population	<p>People (aged 40 years and over) at high risk of dementia in :</p> <ul style="list-style-type: none"> • Primary care • Acute hospitals • Care homes <p>Populations of particular interest include:</p> <ul style="list-style-type: none"> • People over 60 at high vascular risk (e.g. prior stroke) • People with learning disabilities • People with other neurological disorders (e.g. multiple sclerosis)
Intervention	<p>An identification and treatment pathway consisting of:</p> <ul style="list-style-type: none"> • Standard cognitive tests for case finding, with referral to specialist dementia diagnostic services for those found to be positive • Subsequent optimal treatment for people diagnosed with dementia
Comparator	Usual care (including diagnosis of dementia and treatment in people presenting with suspected dementia)
Outcomes	<ul style="list-style-type: none"> • Sensitivity and specificity of case finding • Positive and negative likelihood ratios for case finding • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Structured case finding for dementia is only worth carrying out if it is associated with a change in clinical practice that improves outcomes for the person diagnosed with dementia or their carers. Therefore, it was agreed the most important research to undertake was not in the usefulness of case finding for identifying people with dementia, but instead whether that earlier identification lead to improved outcomes.
Relevance to NICE guidance	Low priority: it was possible to make recommendations in this area, but these could be improved by the existence of more evidence on this specific issue.
Current evidence base	Only a single RCT was identified that that looked at case finding in people at high risk of dementia, as opposed to screening of older people. In addition, there was a lack of evidence on the effects of case finding on the people who were diagnosed with dementia, or their carers, as a result of this intervention.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the difficulty of diagnosing dementia in people with learning disabilities).
Feasibility	There is a large enough population of people at higher risk of dementia that randomised controlled trials in this area should be feasible.

3

L.4.1 Case management

Research recommendation 4	What is the effectiveness and cost effectiveness of high-intensity case management compared with usual care on quality of life (for the person living with dementia and for their carer) and the timing of entry to long-term care?
Population	People (aged 40 years and over) living with dementia and their carers
Intervention	High-intensity case management
Comparator	Usual care, which may consist of either: <ul style="list-style-type: none"> • Lower-intensity case management • No case management
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Entry to long stay care • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	There is evidence that case management is an effective intervention for people living with dementia. However, the effectiveness and cost effectiveness of high-intensity case management has not been tested in the UK. It has a high upfront cost, but there is some evidence from settings outside the UK that it may reduce the use of other services, leading to cost savings across the whole system. Because of the cost, robust evidence of and cost effectiveness from a UK setting is needed.
Relevance to NICE guidance	High priority: new evidence in this area has the potential to allow substantially different and stronger recommendations to be made in this area.
Current evidence base	Although there is evidence on case management that enabled a positive recommendation to be made for its use, the evidence did not allow a recommendation to be made on the intensity of case management, or how it should be organised
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the additional difficulties of case management in people who do not have an informal carer).
Feasibility	There is a large enough population of people living with dementia in the community that randomised controlled trials in this area should be feasible.

3

L.5.1 Care planning in residential care

Research recommendation 5	What are the most effective methods of care planning for people in residential care settings?
Population	People (aged 40 years and over) living with dementia in a residential care setting
Intervention	Structured care planning interventions
Comparator	<ul style="list-style-type: none"> • Other types of care planning • Usual care
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	A large proportion of people diagnosed with dementia will spend at least some of their life in a residential care setting. Therefore, evidence on how best people's care should be planned and coordinated in that setting would be of value to improving people's quality of life.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due to the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	Only very limited evidence was identified in people living with dementia in residential care settings, and therefore the current recommendations had to be extrapolated from the evidence in people in community settings.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the additional difficulties of care planning in people with communication difficulties).
Feasibility	There is a large enough population of people living with dementia in residential care settings that randomised controlled trials in this area should be feasible.

3

L.6¹ Care planning for people without informal carers

Research recommendation 6	What are the most effective methods of care planning for people who do not have regular contact with an informal carer?
Population	People (aged 40 years and over) living with dementia who do not have regular contact with an informal carer
Intervention	Care planning interventions that do not rely on regular contact with an informal carer
Comparator	<ul style="list-style-type: none"> • Other types of care planning • Usual care
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Entry to long stay care • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Many randomised controlled trials of care planning or case management specifically exclude people without an informal carer. Conducting similar studies on case management and care planning for people without an informal carer would fill this gap in the evidence base, and help to identify whether these people have different needs.
Relevance to NICE guidance	High priority: new evidence in this area has the potential to allow substantially different and stronger recommendations to be made in this area.
Current evidence base	Few of the studies identified in this guideline provided relevant evidence to address this issue, as they routinely excluded people without an informal carer from being in the study, often as the carer was needed for data collection purposes within the trial design.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the additional difficulties of care planning in people with communication difficulties).
Feasibility	Initial identification of people with dementia living alone and without an informal carer may be difficult. However, it was agreed this was an important enough issue to identify that this was not a sufficient reason for studies not to be undertaken.

3

L.7₁ Transitions between care settings

Research recommendation 7	What is the effectiveness of structured transfer plans to ease the transition between different environments for people living with dementia and their carers?
Population	People (aged 40 years and over) living with dementia and their carers
Intervention	Structured transfer plans aimed at easing the transition between different environments
Comparator	Usual care
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	There are established harms caused by transitions between care settings for people living with dementia, often as a result of the transition not being coordinated appropriately (e.g. relevant information not being shared). One possible solution to this problem is structured transfer plans, but there are currently no trials looking at the effectiveness of their use.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	No evidence was identified in the guideline that enabled recommendations (either positive or negative) to be made on the use of structured transfer plans.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia (such as the additional difficulties of care planning in people with communication difficulties).
Feasibility	Initial identification of people with dementia living alone and without an informal carer may be difficult. However, it was agreed this was an important enough issue to identify that this was not a sufficient reason for studies not to be undertaken.

3

L.8₁ Pharmacological treatment of DLB

Research recommendation 8	What is the effectiveness of combination treatment with a cholinesterase inhibitor and memantine for people with dementia with Lewy bodies if treatment with a cholinesterase inhibitor alone is not effective or no longer effective?
Population	People (aged 40 years and over) living with dementia with Lewy bodies in whom treatment with a cholinesterase inhibitor alone is not effective or no longer effective.
Intervention	Treatment with a cholinesterase inhibitor and memantine
Comparator	<ul style="list-style-type: none"> • Treatment with a cholinesterase inhibitor alone • Treatment with memantine alone
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Adverse events • Entry to long stay care • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Although no studies were identified where participants were randomised to combination treatment with a cholinesterase inhibitor and memantine, the committee recognised that this option was being used in practice. From their clinical experience, some people do respond to combination treatment, and therefore evidence on its effectiveness would be of value, particularly as the guideline already recommends combination treatment in people with Alzheimer's disease.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	No evidence was identified in the guideline on the co-prescription of cholinesterase inhibitors and memantine in people living with dementia with Lewy bodies.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with dementia with Lewy bodies that randomised controlled trials in this area should be feasible.

3

L.9₁ Anticholinergic burden

Research recommendation 9	Does actively reducing anticholinergic burden in people living with dementia improve cognitive outcomes compared with usual care?
Population	People (aged 40 years and over) living with dementia
Intervention	Active reduction in anticholinergic burden by: <ul style="list-style-type: none"> • A structured assessment of the medicines they are taking that have an anticholinergic effect • Switching where possible to alternative medicines with a lower anticholinergic effect
Comparator	Usual care
Outcomes	<ul style="list-style-type: none"> • Management of the comorbidity for which the medicine is identified • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Adverse events • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Many people living with dementia are still prescribed medicines with a high anticholinergic burden (which can be caused by individual medicines or by combinations of medicines). It is often unclear if this prescribing is appropriate, or whether actively reducing the number of these medicines would improve cognition. Randomised controlled trials could be conducted, using structured tools to assess anticholinergic burden and actively switching medicines if possible. This would help to identify whether cognition can be improved without adversely affecting the management of the conditions these medicines are prescribed for.
Relevance to NICE guidance	High priority: new evidence in this area has the potential to allow substantially different and stronger recommendations to be made in this area.
Current evidence base	Evidence was identified in the guideline to show there are tools that are able to detect anticholinergic burden in people living with dementia, but no evidence was identified on the effectiveness of using those tools prospectively.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible.

3

L.10₁ Community activities

Research recommendation 10	What is the effectiveness of unstructured community activities on wellbeing for people living with dementia?
Population	People (aged 40 years and over) living with dementia
Intervention	Unstructured community group activities
Comparator	Usual care
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Similar effect sizes were found for a range of group, activity based interventions for people living with dementia (e.g. cognitive stimulation, reminiscence therapy, music, exercise, etc.). One possible interpretation is that the benefits of many of these interventions were driven less by the specific content of the interventions, and more by the benefits from support groups more generally. If this is true, these groups could potentially be delivered more cheaply than structured interventions, therefore a larger number of people could have access to them.
Relevance to NICE guidance	Low priority: it was possible to make recommendations in this area, but these could be improved by the existence of more evidence on this specific issue.
Current evidence base	Evidence was identified for a range of structured interventions, but only limited evidence was available on the effectiveness of unstructured group activities.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible.

3

L.11¹ Self-management

Research recommendation 11	What is the effectiveness and cost-effectiveness of self-management training for people living with dementia and their carers?
Population	People (aged 40 years and over) living with dementia and their carers
Intervention	Self-management training for both the person living with dementia and their carer
Comparator	Usual care
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Entry to long stay care • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	The committee considered the evidence on self-management groups was insufficient to make either a positive or a negative recommendation. In particular, self-management interventions were agreed to comprise such a wide range of possible interventions that the literature currently available did not cover the full range of possible interventions adequately to be able to make recommendations.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	Only a very limited number of small studies were identified looking at self-management interventions for people living with dementia
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible.

3

L.12¹ Managing depression and anxiety

Research recommendation 12	What are the most effective psychological treatments for managing depression or anxiety in people living with dementia at each stage of the condition?
Population	People (aged 40 years and over) living with dementia and diagnosed with depression or anxiety
Intervention	Psychological treatments for managing depression or anxiety
Comparator	<ul style="list-style-type: none"> • Other psychological treatments for managing depression or anxiety • Usual care
Outcomes	<ul style="list-style-type: none"> • Anxiety • Depression • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Depression and anxiety are common problems for people living with dementia, and some of the main treatments used in people without dementia (including antidepressants such as sertraline and mirtazapine) were shown to work less well in people without dementia. This increases the importance of optimising non-pharmacological treatment, due to there being less pharmacological treatments available as an alternative.
Relevance to NICE guidance	Low priority: it was possible to make recommendations in this area, but these could be improved by the existence of more evidence on this specific issue.
Current evidence base	Although evidence was identified for the effectiveness of psychological treatments for depression and anxiety in people living with dementia, these studies covered a wide range of different psychological interventions, and therefore it was not possible to make recommendations on what the most appropriate psychological treatment to use is.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible.

3

L.13¹ Managing agitation

Research recommendation 13	What is the effectiveness and cost-effectiveness of dextromethorphan-quinidine for managing agitation in people living with dementia?
Population	People (aged 40 years and over) living with dementia who are diagnosed with agitation
Intervention	Dextromethorphan-quinidine
Comparator	Placebo
Outcomes	<ul style="list-style-type: none"> • Agitation • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Adverse events • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Agitation is a common problem in people living with dementia, and although evidence was identified on effective non-pharmacological management strategies, there is still a need for effective pharmacological treatments if first line non-pharmacological management is not effective.
Relevance to NICE guidance	Low priority: it was possible to make recommendations on managing agitation, but these could be improved by the existence of more evidence on this specific issue.
Current evidence base	One small study on dextromethorphan-quinidine for managing agitation was identified, but further evidence would be necessary in order to be able to make recommendations on its use.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible.

3

L.14¹ Managing apathy

Research recommendation 14	What is the effectiveness and cost-effectiveness of choline alfoscerate for managing apathy in people living with dementia?
Population	People (aged 40 years and over) living with dementia and diagnosed with apathy
Intervention	Choline alfoscerate
Comparator	Placebo
Outcomes	<ul style="list-style-type: none"> • Apathy • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Adverse events • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Apathy is a common problem in people living with dementia, and no evidence is currently available on effective non-pharmacological treatments, increasing the importance of potentially effective pharmacological treatments.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	One small study on choline alfoscerate for managing apathy was identified, but further evidence would be necessary in order to be able to make recommendations on its use.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible.

3

L.15¹ Managing sleep problems

Research recommendation 15	What is the effectiveness of pharmacological treatments for sleep problems in people who have not responded to non-pharmacological management?
Population	People (aged 40 years and over) living with dementia and sleep problems who have not responded to non-pharmacological management
Intervention	Pharmacological treatments for sleep problems
Comparator	Usual care
Outcomes	<ul style="list-style-type: none"> • Sleep quality • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Adverse events • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Sleep problems are common in people living with dementia, and although evidence was identified on effective non-pharmacological management strategies, there is still a need for effective pharmacological treatments if first line non-pharmacological management is not effective.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due to the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	No evidence on effective pharmacological treatments for sleep problems in people living with dementia was identified in the guideline.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible.

3

L.16¹ Managing depression in carers

Research recommendation 16	What is the effectiveness and cost-effectiveness of group-based cognitive behavioural therapy for carers of people living with dementia who are at high risk of developing depression?
Population	Carers of people (aged 40 years and over) living with dementia who are at high risk of developing depression
Intervention	Group-based cognitive behavioural therapy
Comparator	Usual care
Outcomes	<ul style="list-style-type: none"> • Incidence of carer depression • Severity of carer depression • Carer quality of life • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Carers of people living with dementia are at a higher risk of developing depression than the general population. Therefore, prophylactic strategies designed to reduce the incidence of depression diagnosis in the group of people at high risk could not only improve outcomes, but also potentially save money on depression treatment.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	Good quality evidence was identified that group CBT reduces depressive symptoms in carers of people living with dementia. However, these trials were primarily conducted in a broad population of carers without defined symptoms at baseline, and it was agreed to be unrealistic to provide CBT for all carers, regardless of their baseline risk of depression. Therefore, trials conducted specifically in a population at high risk of depression would allow for more targeted recommendations to be made.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of carers of people living with dementia that randomised controlled trials in this area should be feasible.

3

L.17¹ Training community staff

Research recommendation 17	What is the cost effectiveness of using a dementia-specific addition to the Care Certificate for community staff, including dementia-specific elements on managing anxiety, communication, nutritional status and personal care?
Population	Community staff caring for people (aged 40 years and over) living with dementia
Intervention	A dementia-specific addition to the Care Certificate, including dementia-specific elements on managing anxiety, communication, nutritional status and personal care.
Comparator	The existing Care Certificate
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Entry to long stay care • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Robust evidence demonstrates the effectiveness of intensive training for staff heavily involved in providing care and support for people living with dementia. However, it is not clear if it is effective to provide basic training to all staff who come into contact with people living with dementia, or how this training should be provided. One possibility is an expanded version of the Care Certificate that includes additional dementia-specific elements. Because this training would need to be given to a large number of staff, there needs to be good evidence of benefits, specifically in improving quality of life for people living with dementia and their carers, to justify the upfront costs.
Relevance to NICE guidance	High priority: new evidence in this area has the potential to allow substantially different and stronger recommendations to be made in this area.
Current evidence base	Although the evidence currently available did allow for recommendations to be made on the general principles of staff training, it did not allow specific recommendations to be made on how that training should be conducted.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of community staff working with people living with dementia that randomised controlled trials in this area should be feasible.

3

L.18¹ Training hospital staff

Research recommendation 18	What is the effectiveness of training acute hospital staff in managing behaviours that challenge in people living with dementia on improving outcomes for people and their carers?
Population	Acute hospital staff caring for people (aged 40 years and over) living with dementia who exhibit challenging behaviours
Intervention	Training in managing challenging behaviours
Comparator	Usual training
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	People living with dementia are known to have poor outcomes in hospital, and one potentially reason for this is a lack of dementia-specific training for hospital staff. Appropriate training could both improve outcomes for people living with dementia, and allow for people to be more easily and appropriately discharged back in to the community.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	Only very limited evidence was identified on the training of hospital staff – the majority of evidence on staff training came from community or care home setting.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of hospital staff working with people living with dementia that randomised controlled trials in this area should be feasible.

3

L.19¹ Managing delirium superimposed on dementia

Research recommendation 19	What are the most clinically and cost-effective non-pharmacological interventions for helping the long-term recovery of people with delirium superimposed on dementia?
Population	People (aged 40 years and over) diagnosed with delirium superimposed on dementia
Intervention	Non-pharmacological interventions aimed at helping the long-term recovery of people with delirium superimposed on dementia
Comparator	<ul style="list-style-type: none"> • Other non-pharmacological interventions • Usual care
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	The acute management of delirium superimposed on dementia is likely to be similar to the management of delirium in people without dementia. However, there may be differences in the interventions needed to aid long-term recovery, particularly because people with different severities of dementia will have different baseline cognitive status. Research on the most effective non-pharmacological methods of promoting long-term recovery would help to identify whether alternative approaches are needed for people living with dementia.
Relevance to NICE guidance	High priority: new evidence in this area has the potential to allow substantially different and stronger recommendations to be made in this area.
Current evidence base	No evidence is currently available on how the long-term recovery from delirium superimposed on dementia should be managed.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people diagnosed with delirium superimposed on dementia that randomised controlled trials in this area should be feasible.

3

L.20¹ Managing incontinence

Research recommendation 20	What is the effectiveness of interventions to improve faecal and urinary continence in people living with dementia?
Population	People (aged 40 years and over) living with dementia who have faecal and urinary continence issues
Intervention	Interventions to improve faecal and urinary continence
Comparator	Usual care
Outcomes	<ul style="list-style-type: none"> • Faecal and urinary continence • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Incontinence is a common problem in people living with dementia, and one that is known to be associated with increased carer burden and rates of entry to long stay care. Effective interventions to manage incontinence would be expected to improve outcomes for both people living with dementia and their carers.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	Only very limited evidence is currently available on the management of incontinence in people living with dementia, and none that is sufficient to allow recommendations to be made.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with dementia that randomised controlled trials in this area should be feasible.

3

L.21¹ Managing cardiovascular disease

Research recommendation 21	What is the impact on cognition, quality of life and mortality of withdrawing treatments for the primary and secondary prevention of vascular outcomes in people with severe dementia?
Population	People (aged 40 years and over) living with severe dementia who are also at high cardiovascular risk
Intervention	Withdrawal of treatment for the primary and secondary prevention of cardiovascular outcomes
Comparator	Continuation of treatment for the primary and secondary prevention of cardiovascular outcomes
Outcomes	<ul style="list-style-type: none"> • Mortality • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	There are a considerable number of people living with both dementia and a high risk of cardiovascular events. Interventions can reduce the risk of those events, but are often quite intensive and may cause distress or other harms to the person. Therefore, there is a need for evidence on where there is an appropriate time for these interventions to be withdrawn in people living with severe dementia.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	Only very limited evidence is currently available on the management of cardiovascular disease in people living with severe dementia, and none that is sufficient to allow recommendations to be made.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with severe dementia that randomised controlled trials in this area should be feasible.

3

L.22¹ Managing diabetes

Research recommendation 22	What is the impact on cognition, quality of life and mortality of withdrawing intensive treatments for diabetic control in people with severe dementia?
Population	People (aged 40 years and over) living with severe dementia who are also diagnosed with diabetes
Intervention	Withdrawal of intensive treatments for diabetic control
Comparator	Continuation of intensive treatments for diabetic control
	<ul style="list-style-type: none"> • Mortality • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	There are a considerable number of people living with both dementia and diabetes. Interventions can reduce the risk of diabetes associated harms, but are often quite intensive and may cause distress or other harms to the person. Therefore, there is a need for evidence on where there is an appropriate time for these interventions to be withdrawn in people living with severe dementia.
Relevance to NICE guidance	Low priority: it was possible to make recommendations in this area, but these could be improved by the existence of more evidence on this specific issue.
Current evidence base	Only very limited evidence is currently available on the management of cardiovascular disease in people living with diabetes, and none that is sufficient to allow strong recommendations to be made, other than by cross-referencing to the existing NICE guideline on diabetes.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with severe dementia that randomised controlled trials in this area should be feasible.

3

L.23¹ Managing mental health problems

Research recommendation 23	What are the optimal management strategies for people with enduring mental health problems (including schizophrenia) who subsequently develop dementia?
Population	People (aged 40 years and over) who have mental health problems and go on to develop dementia
Intervention	Management strategies for people with enduring mental health problems
Comparator	<ul style="list-style-type: none"> • Other management strategies for people with enduring mental health problems • Usual care
Outcomes	<ul style="list-style-type: none"> • Management of mental health condition • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	A substantial number of people living with dementia also have a comorbid mental health problem that predates their dementia. The management of that mental health problem may need to be modified as the person's dementia becomes more severe, but there is little evidence currently on how best this should be one.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	No evidence was identified in the guideline on the optimal management strategies for people with enduring mental health who subsequently develop dementia
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with dementia who also have a comorbid mental health problem that randomised controlled trials in this area should be feasible.

3

L.24¹ Palliative care

Research recommendation 24	What are the most effective models of general and specialist palliative care support to meet the needs of people with advanced dementia?
Population	People (aged 40 years and over) living with advanced dementia
Intervention	Models of general and specialist palliative care support aimed at people with advanced dementia
Comparator	<ul style="list-style-type: none"> • Other palliative care models • Usual care
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Palliative care is a key part of the support offered to people with advanced dementia, and therefore it is important to maximise the effectiveness of the support provided, including how both general and specialist palliative care services can be coordinated to provide optimal care.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due to the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	Only a small number of trials were identified on specific palliative care interventions for people living with dementia. As a result, whilst it was possible to make recommendations on general principles of palliative care, it was not possible to make specific recommendations on how it should be delivered.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with advanced dementia that randomised controlled trials in this area should be feasible.

3

L.25¹ Recognising end of life

Research recommendation 25	What are the most effective interventions to support staff to recognise advanced dementia and develop appropriate escalation/end of life plans to facilitate care to remain at home?
Population	People (aged 40 years and over) living with advanced dementia
Intervention	Interventions that aim to facilitate care to remain at home by developing escalation/end of life plans
Comparator	<ul style="list-style-type: none"> • Other interventions with the same goals • Usual care
Outcomes	<ul style="list-style-type: none"> • Cognition • Activities of daily living • Behavioural and psychological symptoms of dementia • Quality of life • Entry to long stay care • Carer outcomes • Resource use and costs
Study design	Randomised controlled trials

2

Potential criterion	Explanation
Importance to patients, service users or the population	Recognising when a person living with dementia is approaching end of life can be complex, and as a result it is often not clear wither when end of life plans should be implemented, and what plans are most effective. Effective support programmes for staff could help them to deliver more appropriate and timely care, and improve outcomes for people living with dementia.
Relevance to NICE guidance	Moderate priority: it was not possible to make specific recommendations in this area due the lack of evidence. As a result a suitable study in this area could provide evidence for future recommendations.
Current evidence base	Only a small number of trials were identified on specific palliative care interventions for people living with dementia. As a result, whilst it was possible to make recommendations on general principles of palliative care, it was not possible to make specific recommendations on how it should be delivered.
Equality	No additional equality issues are envisaged relating to this study over and above those applying generally to vulnerable groups of people with dementia.
Feasibility	There is a large enough population of people living with advanced dementia that randomised controlled trials in this area should be feasible.

3