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Hospital design for older people with cognitive impairment including dementia and delirium: supporting inpatients and accompanying persons

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Hospital design for older people with cognitive impairment including dementia and delirium: supporting inpatients and accompanying persons

Abstract

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:. Primary objective. To assess the effects of various built environment interventions, in the form of hospital planning and design approaches and features, on the health and wellbeing of older inpatients with cognitive impairment including dementia and delirium. Secondary objectives. To assess the effects of built environment interventions on accompanying persons. These interventions consist of any design feature that supports an accompanying person as they assist or accompany the patient in the hospital. To assess the effects of built environment interventions on staff within inpatient wards who are providing care to older patients with cognitive impairment. To identify gaps in the evidence and outline topics for future research.

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[Intervention Protocol]

Hospital design for older people with cognitive impairment including dementia and delirium: supporting inpatients and accompanying persons

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

Primary objective

To assess the effects of various built environment interventions, in the form of hospital planning and design approaches and features, on the health and wellbeing of older inpatients with cognitive impairment including dementia and delirium.

Secondary objectives

- To assess the effects of built environment interventions on accompanying persons. These interventions consist of any design feature that supports an accompanying person as they assist or accompany the patient in the hospital.
- To assess the effects of built environment interventions on staff within inpatient wards who are providing care to older patients with cognitive impairment.
- To identify gaps in the evidence and outline topics for future research.

BACKGROUND

Cognitive impairment is common among older patients within hospitals, and arises from a range of syndromes: from intellectual disability and acquired brain injury to dementia and delirium. The complex and challenging nature of the hospital environment can significantly undermine the ability of a person with a cognitive impairment to find their way around, feel at ease, and thrive to the greatest extent possible.

The need to improve hospital environments for patients with cognitive impairment is receiving greater public attention, not least because of the increased awareness of the high levels of dementia and delirium among older patients. The most common way of describing the responses to this need is to refer to the provision of 'dementia-friendly design'.

Although this description has some inherent limitations (such as potentially adding to stigma, or appearing exclusive), for the purposes of this Cochrane Review it is a useful and prevalent pragmatic descriptor for inclusive design that pays attention to cognitive impairment. In this regard, many of the issues addressed by dementia-friendly design are common to the underlying syndromes related to cognitive impairment. A further benefit of considering the issue of cognitive impairment under the label of dementia is due recognition of the comorbidities that commonly accompany dementia and delirium, in effect representing the most complex challenges to inclusive hospital design. For these reasons, we will draw on well-established dementia-friendly design principles to structure this review.

Furthermore, to ensure that this review is focused and manageable, we will concentrate on older patients (typically over 65 years of age) with cognitive impairment including dementia and delirium in adult acute care hospitals within inpatient wards. While these are the focus of this review, there may be scope in future reviews to look at other patient groups and other departments, wards, or public areas within the hospital.

Description of the condition

Demographic ageing means that hospitals are treating an increasing percentage of older people; for instance in the Republic of Ireland in 2015, people over 65 years of age accounted for 54% of the total hospital inpatient bed days and approximately 37% of day case bed days (HSE 2017). In line with this, the percentage of hospital patients with cognitive impairment has grown. Some hospital-based studies have found that cognitive impairment was present in over 38% of patients over 65 years old, and in over 50% of patients over 85 years old (Reynish 2017). Research specific to dementia shows that up to 30% of all inpatients in acute hospitals have dementia (de Suin 2014; George 2013), while other research suggests these figures may be higher (Torian 1992).

Overlap between cognitive impairment, dementia, and delirium

Cognitive impairment is a broad term referring to difficulties in processing thoughts that lead to memory loss, impaired decision making, inability to concentrate, and learning difficulties. Although cognitive impairment is not a normal part of ageing, it is common in hospitalised older patients, with dementia and delirium the most frequent causes (Travers 2013). Patients with dementia may also experience gait disorders that impact mobility and stability while

walking; muscular strength loss and associated functional decline (Rogers 2008); and visual and perception issues related to visuospatial and visuoperceptual defects (Possin 2010). They are at increased risk of preventable complications and adverse events, such as falls and pressure injuries, and require precautions to prevent harm (Inouye 2014; Mukadam 2010). It is often difficult to distinguish between dementia and delirium because of the overlap of symptoms and this is complicated by the fact that they frequently co-exist (Fong 2015).

Impact of the hospital setting

For many people, hospitals can prove challenging due to the change of environment and factors such as stress and sleep deprivation (Hanley 2004). For a person who is cognitively impaired, negative health outcomes can be intensified (Waller 2013). Furthermore, when a cognitively impaired person becomes hospitalised for another health issue but without their cognitive impairment, for instance dementia, having been diagnosed, the situation can become worse and may lead to additional problems such as over- or under-medication, injuries, or malnutrition (Galvin 2010).

Moyle 2008 argues that many hospitals are not designed to care for people with dementia, and this undermines their care and adds to the burden of care for hospital staff. Negative factors in a typical hospital can include communication difficulties due to the noisy hospital setting, and multiple and competing stimuli that can be very stressful for people who are cognitively impaired.

The overall scale, complexity, and excessive institutional atmosphere of many hospitals has adverse outcomes for all types of occupants, including anxiety and a lack of perceived personal control (Jiang 2017). This can be exacerbated for a person who is cognitively impaired due to the unfamiliar and intimidating nature of such a complex setting (Fleming 2014; Waller 2013). Furthermore, for a person who is experiencing amnesia and agnosia, which are symptoms common to dementia (Burns 2001), the scale and complexity of a large-scale building may be additionally stressful and disorientating in terms of time and place (van Hoof 2014).

Reduced activity and mobility are common among older hospitalised patients and often result in deconditioning, functional decline, and complications such as dehydration, malnutrition, or delirium. Hospital-related functional decline is more pronounced among cognitively impaired patients and has been linked to impaired activities of daily living (ADL) on discharge (Kleinpell 2008). Aligned with this, the Royal College of Psychiatrists 2013 warns that inactivity in older patients can lead to a lack of attention, lack of stimulation, and boredom. While there are many clinical reasons for reduced activity and mobility, there are many contributing physical environment factors such as the absence of social areas and space to mobilise, or staff reluctance to let patients move around due to safety and security concerns (Baillie 2012).

Lack of natural light and lack of views to the outside environment have been linked to prolonged patient recovery times (Ulrich 2008). Despite the increased awareness of the impact of the sensory environment, Malenbaum 2008 warns that many hospital rooms do not provide the sensory distractions required to alleviate pain.

Grinde 2009 argues that any environment devoid of nature or access to outdoor space creates a 'discord' and undermines health and wellbeing. Yet many hospitals do not utilise or properly re-

source outdoor space or garden areas (Górska-Kłęk 2013; Whitehouse 2001). Hartig 2006 argues that a disregard for therapeutic gardens in hospitals is highlighted by minimal planting and restricted access to these spaces.

Hospitals and the supportive role of accompanying persons

The quality of relationships between patients, family members, and staff influences cognitive decline, quality of life, and other outcomes in people with dementia (Benbow 2014; Burgener 2002; Rushton 2016). On a practical level, an accompanying person (typically a person such as a family member, close friend, or professional carer external to the hospital) can physically help the patient and also ease the hospital experience for the patient by providing a familiar face and voice (Li 2003). They can also provide valuable information to the staff regarding the patient's needs, preferences, and usual behaviour patterns and thus contribute to individualised care plans (Moyle 2008). At the same time, however, the accompanying role can be stressful and demanding (Digby 2014; Livingston 2017).

Unfortunately, this role is often undermined within the hospital setting (Li 2003), with Rushton 2016 arguing that important relationships between patients and others are curtailed. In many cases, this is due to a loss of control experienced by patients, an unfamiliar environment, and an overall disruption of the family dynamic through hospitalisation.

Description of the intervention

With a growing awareness of the negative impact of the hospital environment on older people, initiatives such as the 'Age-Friendly Hospital' have developed (Chiou 2009; Huang 2011). In terms of the physical environment, these initiatives typically include the application of universal design (Kose 2001), or inclusive design, the installation of easy to read wayfinding signage, high quality lighting, non-slip floors, handrails within circulation areas such as corridors, and the provision of comfortable and accessible waiting areas.

In parallel with these initiatives, a range of design initiatives and guidelines have been developed in recent years with a specific focus on older people with cognitive impairment, and dementia in the hospital setting (DSDC 2012; Fleming 2014; Waller 2013). These initiatives promote enhanced legibility, orientation, and wayfinding; they increase familiarity; provide opportunities for movement and engagement, and meaningful activity; unobtrusively reduce risks for patients; provide a human scale; reduce unhelpful stimulation and optimise helpful stimulation; provide a variety of places to be alone or with others; and provide links to the community.

The various design principles discussed above have been applied across a wide spectrum of spaces in the hospital from circulation areas and individual waiting areas or bedrooms, to outdoor spaces, and entire wards. They have been applied to both small scale retrofit and to larger redevelopment or new build projects, and from general inpatient wards to age-related or geriatric wards (Department of Health and Social Care (UK) 2015; Waller 2013).

Many hospital design initiatives that focus on older people with cognitive impairment are part of, or are triggered by, broader models of care such as the Hospital Elder Life Program (HELP), Progressively Lowered Stress Threshold (PLST), or Creating Avenues for Relative Empowerment (CARE) (Moyle 2008). More recently, in Australia, the Dementia Care in Hospitals Program (DCHP) has been implemented across a number of states to provide greater aware-

ness and additional supports for people with cognitive impairment in hospitals (Yates 2018). In the Republic of Ireland, the Health Service Executive (HSE) and Genio Dementia Programme 2012 to 2018 contained a strand focusing on 'Integrated care pathways in the acute hospital sector for people with dementia'. This included mapping and analysis of patient pathways, enhanced admission and discharge processes, staff awareness and training, and other dementia-related improvements. Dementia-friendly design was a key component in this programme and this illustrates how design changes are often part of improved models of care in the acute setting (Grey 2018b).

Specialised units within hospitals have also been developed using various iterations of these dementia-friendly design principles and features. One of the earliest models appeared in the USA in the form of Acute Care for Elders (ACE) units that provided care for acutely ill patients with dementia and were designed to prevent cognitive and functional decline during a hospital stay (Fox 2013). Since then, similar models have been developed internationally (Flood 2018), and these generally create more home-like, calm, and spacious settings that support physical and cognitive functioning (Lim 2005; Palmer 2018).

How the intervention might work

Many studies link better patient and staff outcomes to various built environment features, such as the presence of windows (Keep 1980), views to nature (Ulrich 1984), the level of sunshine in rooms (Beauchemin 1996), art interventions (Staricoff 2003), or single versus multiple occupancy rooms (Shirani 1986). Social outcomes have been linked to the provision of adequate space for privacy or engagement with families and friends (Sakallaris 2015; Setola 2016). Furthermore, cognitive functioning can be improved through legible and coherent hospital layouts and materials, finishes, and signage that support spatial cognition, orientation, and wayfinding for occupants (Marquardt 2014; Passini 1998; Setola 2016).

Outcomes may also be related to indirect built environment effects on mental health and psychological wellbeing (Evans 1998; Evans 2003). Ulrich's 'Theory of Supportive Design' proposes that health-care environments will foster improved outcomes if they support stress reduction, buffering, and coping in patients (Ulrich 2001). Along similar lines, proponents of salutogenics, which is a psychosocial approach to human health, argue that a sense of coherence is critical to mental health (Antonovsky 1986). This sense of coherence, which is supported by feelings of comprehensibility, manageability, and meaningfulness, has been applied to architecture and a salutogenic design approach has emerged with the aim of improving health outcomes in the built environment (Golembiewski 2010).

The manner in which a hospital building facilitates contact with nature is also receiving more attention. The concept of biophilia is important here, which is a term initially introduced by Fromm 1973 and promoted by Wilson 1995 who described biophilia as the innate emotional affiliation that human beings have with other living organisms. It is argued that contact with nature and a fulfilment of this biophilic relationship influences our health and wellbeing (Kellert 2012). While research is still needed in this area, studies by Ulrich 2008 and others (Frumkin 2001; Grinde 2009) have found positive links between health and nature. In terms of architecture, these theories have been translated as 'biophilic design' in an effort to

ensure that the built environment supports and promotes contact with nature as part of a healthful design approach (Kellert 2012; McGee 2015).

Patient access to outdoor space provides physical exercise (Lindenmuth 1990), space to socialise (Rappe 2007), therapeutic activities (Gibson 2007), exposure to natural light (Brawley 2002), or helps restore attentional capacity (Kaplan 1995; Moore 2007).

The outcomes discussed above have particular relevance for older people with cognitive impairment as they are often more susceptible to a negative environment, have a lower stress threshold, and are in need of greater physical, sensory, cognitive, and social support. In this regard, Fleming 2017 argues that a well-designed environment works better for people who are cognitively impaired by improving wayfinding, eating behaviour, motor functions, ADL, mobility, social interaction, and quality of life. At the same time, a well-designed environment may reduce agitation, anxiety, confusion, number of falls, and requirements for psychotropic drugs.

Why it is important to do this review

Frumkin 2003 argues for a better use of evidence to underpin design decisions; an approach strongly advocated by Hamilton 2009. This is particularly relevant when designing inclusive hospital environments for people who are cognitively impaired, given their sensitivity to the built environment and vulnerability in the hospital context. The relationship between older patients with cognitive impairment and the acute hospital setting, coupled with how the hospital environment can either greatly hinder or help with their treatment, demands a rigorous, evidence-based approach to design. While high-quality literature reviews have been conducted looking at the impact of the built environment on people with dementia (Day 2000; Fleming 2008; Marquardt 2014), there are few with a specific focus on the hospital environment. In addition, the application of the rigorous Cochrane methodology will strengthen the findings and make them available to a wider audience.

OBJECTIVES

Primary objective

To assess the effects of various built environment interventions, in the form of hospital planning and design approaches and features, on the health and wellbeing of older inpatients with cognitive impairment including dementia and delirium.

Secondary objectives

- To assess the effects of built environment interventions on accompanying persons. These interventions consist of any design feature that supports an accompanying person as they assist or accompany the patient in the hospital.
- To assess the effects of built environment interventions on staff within inpatient wards who are providing care to older patients with cognitive impairment.
- To identify gaps in the evidence and outline topics for future research.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials and cluster-randomised controlled trials to assess the effectiveness of interventions. However, due to the challenges associated with conducting these trials for built environment interventions and the lack of studies in this context, we will also include a range of non-randomised trials, controlled before-and-after studies, interrupted time series studies, and repeated measures studies that compare typical inpatient wards or built environment features to alternative wards or features. We will include peer-reviewed articles, conference papers, and unpublished data if we can obtain the data from the study authors. There will be no language restrictions.

Types of participants

We will focus on the following participants.

- Older patients: ageing populations, the growing numbers of older patients in hospitals, and their vulnerability to the hospital environment (Goldberg 2013), make older patients an important group to focus on. We will include all older hospital inpatients (typically over 65 years of age), regardless of medical condition/treatment, who have a diagnosed or suspected cognitive impairment including dementia and delirium.
- Accompanying persons: we will include accompanying persons, such as family or friends who assist or accompany the patient during their stay in the hospital.
- Staff: we will also include staff working within inpatient wards providing care to older patients with cognitive impairment.

Types of interventions

Interventions

In this review we will focus on adult acute hospitals and look specifically at inpatient wards. The rationale for this focus is as follows.

- Adult acute care hospitals: these hospitals are designed to deliver time-sensitive acute curative services often in a rapid manner, as opposed to other healthcare settings such as primary healthcare centres (i.e. designed primarily for short daytime visits) or community hospitals (i.e. often providing long-term residential care or rehabilitation). Acute hospitals are a critical part of any health service and will experience greater demand as populations increase and grow older (Hirshon 2013).
- Inpatient wards: inpatients may spend a number of days in the hospital and will experience sleeping, bathing, dining, and other ADL within the inpatient ward. Therefore, the quality of this environment is very important, particularly for older patients with cognitive impairment who often have an extended length of stay within the inpatient ward (Connolly 2015).

We will assess studies that include interventions to existing inpatient wards and also those looking at new-build inpatient wards that are explicitly designed to provide greater support for older patients with cognitive impairment. Given the wide range of potential interventions that may be implemented, we have examined the literature to create a framework of key design issues and desired outcomes to structure the review, select relevant studies, identify interventions, and frame the analysis. The design issues in this

framework are drawn from well-established literature relating to diverse healthcare environments (Calkins 2001; Cohen 1991; Fleming 2014; Marshall 1998), design guidelines for care home and domestic settings (DSDC 2013; Lawton 2001; Pierce 2014; van Hoof 2014), and recent guidelines around dementia-friendly hospital design (Department of Health and Social Care (UK) 2015; DSDC 2012; Grey 2018a; King's Fund 2014; Takeda 2010). We have selected a number of key design issues from this literature and grouped these into seven themes as listed below. We have included possible design approaches or interventions with each theme to provide examples of the types of interventions we will cover in this review.

Design themes

• Support engagement and participation

- * Provide a physical environment and adequate space to promote engagement with friends and family, staff, and community. Typical interventions include communal rooms for social engagement or community based activities, images of the locality within bedrooms, circulation areas or communal spaces to promote community connections and engagement.

• Provide a people-centred environment

- * Soften the institutional environment. Typical interventions include smaller ward size or breaking wards down into smaller units; provision of more home-like (or less clinical or institutional) colours, finishes, fittings, furniture; more welcoming nurses station or dispersed rather than large centralised nurses stations.
- * Provide familiar design. Typical interventions include taps, door handles, or other fittings that are recognisable and intuitive to use.
- * Facilitate personalisation within the ward. Typical interventions include dedicated locker space or wall space for memorabilia, family photos, or similar objects that have a personal meaning.

• Support patient safety, wellbeing, and health

- * Provide a safe environment. Typical interventions include hand and grab-rails for stability, non-slip floors, or unobtrusive safety features that prevent a person leaving the ward if it is not safe for them.
- * Provide adequate space and environmental conditions to support diet, nutrition, and hydration. Typical interventions include a dedicated dining room or familiar and home-like dining tables and chairs.
- * Provide space and supports for meaningful activities. Typical interventions include kitchen within family room to allow a person make a cup of tea or wash dishes, or the provision of an outdoor space to carry out light gardening activities or other such activities associated with home.
- * Provide a high-quality sleep environment. Typical interventions include single rooms, good acoustic design to create a quiet setting, or careful artificial lighting design that balances good sleep conditions with patient observation.

• Balance sensory stimulation

- * Optimise positive sensory stimulation. Typical interventions include window design that admits pleasant daylight, a gentle breeze from outside, or the sounds of nature such as bird-song.
- * Minimise negative stimulation. Typical interventions include windows that control excessive glare or heat gain, acoustic

panels that absorb sound, the design and installation of silent running equipment, or responsive and easily controlled heating and ventilation systems.

- * Provide contact with nature. Typical interventions include good views to nature, internal planting or images of nature used within the ward.
- * Provide access to outdoor space to support active and passive therapeutic activities. Typical interventions include accessible, usable, and easily understood garden spaces directly accessed from the ward, balconies, or roof terraces.

• Support legibility, orientation, and navigation

- * Provide a clearly legible environment. Typical interventions include good colour contrast between walls and floors so that key building elements are legible and spaces are easily understood.
- * Enhance orientation to date, time, and location. Typical interventions include large format clocks and calendars, external views to prominent local features or landmarks, or internal images of the local context.
- * Provide good wayfinding that supports navigation. Typical interventions include use of colour panels or doors as a visual cue to the location of an object or space such as a toilet, wayfinding signage, images, or symbols to provide directional information.
- * Provide good visibility and visual access. Typical interventions include direct views from a bed to the toilet door as a visual cue, glazed internal doors or panels to provide views into communal rooms from corridors, glazed doors to wardrobes or kitchen units to provide views to contents.

• Adequate space to support the particular needs of a person with a cognitive impairment

- * Space for personal belongings. Typical interventions include a good level of storage within rooms, large lockers, or shelves for personal belongings.
- * Adequate room for visitors. Typical interventions include space and seating beside beds, smaller intimate seating areas within shared patient rooms or along corridors where patients can sit and chat with visitors.
- * Space for retreat in multi-bed wards. Typical interventions include family rooms or quiet rooms to get a break from a busy shared ward (as a respite from sensory overload in noisy multi-bed wards).
- * Communal areas in single-bed wards. Typical interventions include social spaces or small seating areas in the circulation areas where a person in a single room can socialise and partake in activities (to provide sensory stimulation and prevent isolation).
- * Space and supports for patient mobilisation and activities. Typical interventions include generous circulation areas that encourage walking within the ward, handrails along corridor for stability, small seating and interest areas along corridors to provide resting and destination points.

• Space and supports for accompanying persons and staff

- * Provide space and supports so that accompanying persons can remain with the patient, where possible, throughout their time in the ward. Typical interventions include adequate space and seating beside beds, storage within bedrooms for accompanying persons, or a family room where

an accompanying person can take a break, sleep, or have a shower.

- * Provide space and supports for staff providing care to older patients within the inpatient ward. Typical interventions include staff respite rooms, patient hoists, or 'patient-at-a-glance' boards.

We will assess studies that examine whole-ward applications to general wards, and also studies that focus on specialised wards such as geriatric wards or ACE units (See [Description of the intervention](#) for information on these wards). We will also look at specific or individual interventions from across the spatial scale of the ward including ward location and approach; ward entry and internal circulation, key internal and external ward spaces; building components (e.g. materials, finishes, fit-out); and internal environment (e.g. thermal comfort, ventilation, lighting, acoustics).

Control interventions and comparator settings

Control interventions or comparator settings will include usual care environments or hospital settings not specifically designed to cater to the needs of older patients with a cognitive impairment. This may involve pre- and post-evaluation of the same setting or a comparable setting in another part of the hospital or in a different hospital.

Types of outcome measures

Primary outcomes

The primary outcomes relate to patients and include:

- Health-related quality of life, measured using EuroQol, Dementia Care Mapping (DCM), or similar.
- Measures of behaviour and mood, as measured by tools such as the Cohen-Mansfield Agitation Inventory.
- Quality of sleep, using methods such as patient self-reporting and staff observation.
- Incident delirium.

Serious adverse effects will include:

- Patient falls and accidents.

Secondary outcomes

Outcomes relating to accompanying persons will include:

- Carer mood or depression, measured using scales such as the Hospital Anxiety and Depression Scale or the Family Caregiving Burden Inventory.

Outcomes relating to staff will include:

- Staff burnout or work satisfaction, using methods such as the Maslach Burnout Inventory Human Service Survey (MBI-HSS) or the Satisfaction in Nursing Care and Work Scale.

We will determine the threshold for appreciable change or the effect magnitude for each primary and secondary outcome by the specific measurement tool protocols or standards, or those defined in the relevant studies.

We will concentrate on studies where the above outcomes are assessed during the patient's acute hospital admission.

Search methods for identification of studies

Electronic searches

We will search ALOIS (www.medicine.ox.ac.uk/alois), which is the Cochrane Dementia and Cognitive Improvement Group's Specialised Register.

ALOIS is maintained by the Information Specialists of the Cochrane Dementia and Cognitive Improvement Group and contains dementia and cognitive improvement studies identified from the following.

- Monthly searches of a number of major healthcare databases: MEDLINE, Embase, CINAHL, PsycINFO, and LILACS
- Monthly searches of a number of trial registers: meta Register of Controlled Trials; Umin Japan Trial Register; World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) portal (which covers ClinicalTrials.gov, ISRCTN, Chinese Clinical Trials Register, German Clinical Trials Register, Iranian Registry of Clinical Trials, the Netherlands National Trials Register, plus others)
- Quarterly search of the Cochrane Library's Central Register of Controlled Trials (CENTRAL)
- Six-monthly searches of a number of grey literature source: ISI Web of Science Conference Proceeding.

To view a list of all sources searched for ALOIS, see 'About ALOIS' on the ALOIS website.

We will perform additional separate searches in many of the above sources to ensure that we retrieve the most up-to-date results. The search strategy that will be used for the retrieval of reports of trials from MEDLINE (via the Ovid SP platform) is in [Appendix 1](#).

We will also consult the Cochrane Effective Practice and Organisation of Care (EPoC) Information Specialist to ensure the search strategy captures all relevant studies.

Searching other resources

We will assess the reference lists of included studies, and examine relevant grey literature from established and relevant organisations. We will correspond with researchers working in the area for additional information about potential studies for inclusion in this review.

While ALOIS contains references from many databases that contain many key design and architecture titles, we will also search the following databases: Scopus, Academic Search Complete; Science Direct; and ProQuest (these databases will include references to relevant journals such as HERD, PLOS One, Health and Place, and other relevant titles).

Data collection and analysis

Selection of studies

The Cochrane Dementia and Cognitive Improvement Group's information specialist will run the electronic searches and two review authors will assess the results. We will import references into Covidence for subsequent screening. Two review authors will independently screen the articles by title and abstract to identify eligible studies for inclusion. This process will involve a 'no', 'yes', or 'maybe' vote. We will obtain full-text papers of all 'yes' and 'maybe' deci-

sion papers. Two review authors will independently assess the full-text of the 'maybe' studies in greater detail; where a decision cannot be reached, a third review author will decide. We will link multiple reports of the same study and the entire selection process will be carefully documented in a PRISMA diagram. Where included full text papers are not in English, we will get them translated into English.

Data extraction and management

Included studies will probably be highly heterogeneous and many of these studies will probably refer to multiple interventions. For these studies, two review authors will map the interventions and outcomes contained in the studies according to the seven key themes identified (see [Types of interventions](#)), and will extract data accordingly. We will add additional themes and design issues as required for interventions and outcomes that fall outside the seven themes listed. Where the interventions themselves are multi-faceted, we will further organise these into subthemes according to their relationship to the built environment. These subthemes will include spatial layout and building form; materials and finishes; furniture, fixtures and fittings; environmental conditions; and orientation and wayfinding components.

Two review authors will independently extract data from the included studies using Covidence. Where there is disagreement about relevant data to be extracted, a third review author will arbitrate. We will extract data according to the *Cochrane Handbook for Systematic Reviews of Interventions* Chapter 7.3 ([Higgins 2011](#)) to include source, eligibility, methods, participants, interventions, comparators, outcomes, results, and miscellaneous notes. Where possible, we will collect ward data regarding the model of care or changes to existing models, number of beds per ward, staff-patient ratio, relevant organisational policies that affect ward access such as visiting times, practices around locking doors, therapeutic activities offered, and other care-related aspects that are closely linked to the performance of the built environment.

Assessment of risk of bias in included studies

For randomised controlled trials, we will use the Cochrane Risk-of-bias tool for randomised trials (RoB 2) to assess bias, as outlined in Chapter 8 of the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2019b](#)). This will involve the five bias domains, including bias due to the randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome, and bias in selection of the reported result. We will use the variants of the RoB 2 tool as set out in Chapter 23 of the *Cochrane Handbook for Systematic Reviews of Interventions* to assess bias in cluster-randomised trials and crossover trials ([Higgins 2019a](#)). We will judge the risk of bias as either low, some concerns, or high risk of bias. We will exclude studies judged to be high risk of bias.

For non-randomised studies, such as observational studies or quasi-experimental studies, we will use the Cochrane Risk of Bias In Non-randomised Studies of Interventions (ROBINS-I) tool, as described in Chapter 25 of the *Cochrane Handbook for Systematic Reviews of Interventions* ([Sterne 2019](#)). We will judge the risk of bias in these studies as either low, moderate, serious, or critical. We will exclude studies that we judge to have a critical risk of bias.

For both randomised and non-randomised studies, we will also refer to guidance from the Cochrane EPOC group document 'Suggest-

ed risk of bias criteria for EPOC reviews' ([EPOC 2017](#)). We will resolve differences of opinion through a third review author or by consensus.

Measures of treatment effect

We will use Review Manager 5 to conduct statistical analysis on the data relating to pre- and post-intervention outcomes, or values for outcomes relating to interventions and control groups ([Review Manager 2014](#)). For dichotomous data, we will measure the effect size using risk ratios (RR) with a 95% confidence interval (CI). We will measure continuous data using standardised mean differences (SMD) with a 95% CI.

Unit of analysis issues

The unit of analysis is the older patient with a cognitive impairment, the accompanying person, and staff members. However, we will collect data from studies based on individual or group outcomes. For cluster-randomised trials, where possible, we will extract data that is adjusted to take account of the clustering effect. In studies where the data is not adjusted to take account of the clustering effect, we will calculate an effective sample size by dividing the original sample size by the design effect as detailed in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)).

For crossover trials, we will use data from the first period. We will divide studies that have more than one intervention group as per [Deeks 2017](#).

Dealing with missing data

Where necessary, we will contact study authors to see if missing data is available. We will record all missing data and any cases of data imputation, along with the imputation methodology.

Assessment of heterogeneity

Considering the breadth of possible interventions, there will potentially be a high level of variability in the results. We will evaluate the clinical, methodological, and statistical heterogeneity based on the type of intervention, participant, and outcomes. We will use the Chi² test and visual inspection of forest plots generated within RevMan 5 to assess the level of heterogeneity in the data ([Review Manager 2014](#)).

Assessment of reporting biases

We will minimise reporting bias by including both published and unpublished studies. Where 10 or more studies meet the inclusion criteria, we will use a funnel plot and Egger's test to assess reporting bias through plot asymmetry. We will assess titles and abstracts in all languages and we will obtain translations of non-English language full-text papers included in the review.

Data synthesis

As described in the [Data extraction and management](#) section, we will extract data from each study and group this data according to the seven key themes identified (see [Types of interventions](#)), or additional themes as necessary. Where there is pronounced clinical heterogeneity in the interventions, these themes will allow us perform separate meta-analyses for each grouping.

We will use GRADEpro GDT to evaluate the quality of the evidence data for the outcomes (i.e. high, moderate, low, and very low) (GRADEpro GDT: GRADEpro Guideline Development Tool), arising from the various themes as per Schünemann 2017.

Where homogenous data is available, we will conduct a meta-analysis on data within these groups using RevMan 5 (Review Manager 2014), as outlined by Deeks 2017. Where a high level of heterogeneity exists, we will use forest plots while also presenting the data in a narrative form with supporting tables. This narrative summary will be based on the themes and will be supported by harvest plots to graphically illustrate the results. Harvest plots have been developed to convey complex interventions and results (Ogilvie 2008), and been successfully used in Cochrane Reviews where there is substantial clinical heterogeneity in the results (Turley 2013).

Subgroup analysis and investigation of heterogeneity

Where there is sufficient data, we will conduct subgroup analysis to focus on patients and accompanying persons in specific types of inpatient wards including: a) general inpatient wards; b) geriatric wards; or c) ACE units. We will explore heterogeneity within these subgroups through the Chi² test and visual inspection of forest plots generated within RevMan 5 (Review Manager 2014). We will develop a narrative summary for these subgroups and these

will be supported by harvest plots to help graphically illustrate the results.

Sensitivity analysis

For studies that are at a high risk of bias, we will undertake sensitivity analysis to test the influence, bias, and robustness of the studies. We will use GRADEpro GDT to evaluate the quality of the evidence data for the outcomes (i.e. high, moderate, low, or very low) arising from the various themes (GRADEpro GDT: GRADEpro Guideline Development Tool), as per Schünemann 2017.

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APPENDICES

Appendix 1. MEDLINE search strategy

- 1 exp Architectural Accessibility/
- 2 exp Environment Design/
- 3 exp Evidence-Based Facility Design/
- 4 exp "Facility Design and Construction"/
- 5 exp Health Facility Environment/
- 6 exp "Hospital Design and Construction"/
- 7 exp "Interior Design and Furnishings"/
- 8 exp Spatial Behavior/
- 9 exp Spatial Learning/
- 10 (Design adj3 institution).tw.
- 11 (hospital* adj7 (Navigation or Orientation or Navigat* or Architectur*)).tw.

12 ("Building design" or "Design approach" or "Design intervention*" or "Environmental communication" or "Environmental design" or "Facilities design" or "facility planning" or "Hospital design" or "Hospital environment" or "Interior design" or "internal environment" or "Patient centred design" or "physical environment" or "Sensory environment" or Signage or "Spatial organisation" or "Spatial organization" or "Supportive design" or "Therapeutic design" or Wayfinding).tw.

13 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12

14 Dementia.tw.

15 Delirium.tw.

16 Wernicke Encephalopathy.tw.

17 ("benign senescent forgetfulness" or ("normal pressure hydrocephalus" and "shunt*") or ("organic brain disease" or "organic brain syndrome") or ((cerebral* or cerebrovascular or cerebro-vascular) adj2 insufficien*) or (cerebr* adj2 deteriorat*) or (chronic adj2 (cerebrovascular or cerebro-vascular)) or (creutzfeldt or jcd or cjd) or (lewy* adj2 bod*) or (pick* adj2 disease) or alzheimer* or binswanger* or deliri* or dement* or huntington* or korsako*).tw.

18 14 or 15 or 16 or 17

19 13 and 18

CONTRIBUTIONS OF AUTHORS

T Grey, R Fleming, and D O'Neill developed the main concept. T Grey prepared the draft manuscript, and all protocol authors assessed and approved the final protocol.

DECLARATIONS OF INTEREST

T Grey: none known.

R Fleming: none known.

B Goodenough: none known.

D Xidou: none known.

R Möhler: none known.

D O'Neill: none known.

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