

BMJ Open Effectiveness of technology-based interventions in detection, prevention, monitoring and treatment of patients at risk or diagnosed with mild cognitive impairment: protocol for a systematic review

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ABSTRACT

Introduction The gradual changes over the decades in the longevity and ageing of European society as a whole can be directly related to the prolonged decline in the birth rate and increase in the life expectancy. According to the WHO, there is an increased risk of dementia or other cognitive disorders as the population ages, which have a major impact on public health. Mild cognitive impairment (MCI) is described as a greater than expected cognitive decline for an individual's age and level of education, but that does not significantly interfere with activities of daily living. Patients with MCI exhibit a higher risk of dementia compared with others in the same age group, but without a cognitive decline, have impaired walking and a 50% greater risk of falling.

The urban lifestyle and advent of smartphones, mobility and immediate access to all information via the internet, including health information, has led to a totally disruptive change in most general aspects.

This systematic review protocol is aimed at evaluating the effectiveness of technology-based interventions in the detection, prevention, monitoring and treatment of patients at risk or diagnosed with MCI.

Methods and analysis This review protocol follows the recommendations of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols reporting guidelines. The search will be performed on MEDLINE (PubMed), CENTRAL, CINAHL Plus, ISI Web of Science and Scopus databases from 2010 to 2020. Studies of interventions either randomised clinical trials or pre-post non-randomised quasi-experimental designs, published in English and Spanish will be included. Articles that provide relevant information on the use of technology and its effectiveness in interventions that assess improvements in early detection, prevention, follow-up and treatment of the patients at risk or diagnosed with MCI will be included.

Ethics and dissemination Ethics committee approval not required. The results will be disseminated in publications and congresses.

Strengths and limitations of this study

- Criteria and data points valid for a systematic review and meta-analysis were followed.
- Databases and search strategies were selected and designed by an expert.
- A blinded peer review will be conducted using a rigorous and consistent set of criteria.
- The effectiveness and use of technologies are questioned and more research is needed.

INTRODUCTION

The WHO indicated that the definition of 'older persons' or 'elderly' is controversial; as each country has established different criteria for categorising a person within a chronological age. Most of the world's advanced countries have accepted that the term 'older person' should correspond to a person over 65 years of age; however, this criterion cannot be applied globally, as it would not correspond to the African countries. In contrast, the United Nations Organisation established a standard numerical criterion, which categorises people over 60 years of age as elderly.¹

The gradual change over the decades in the longevity and ageing of European society as a whole can be directly linked to the prolonged decline in the birth rate and increase in life expectancy. The data show that this trend will be perpetuated over a long period.^{2,3}

Furthermore, future projections of the European Statistical Office (Eurostat)² have indicated that this ageing trend will increase, with people aged 65 years and over accounting for 29.1% of the total population in 2060 and

indicated a significant increase in the population aged over 80 years, which will reach a percentage of 14.6% of the total population in 2100. There are two main factors directly related to this trend in the European regions: (1) the dynamics of fertility and life expectancy at birth and (2) improvements in health and quality of life standards.³

Another report published by Eurostat during 2015 highlighted the increase in the percentage of people living alone across Europe. Improvements in technology, communication, resources, infrastructure and environmental factors benefit and possibly facilitate life in solitude.

The southern European countries, such as Cyprus, Portugal, Greece and Spain show a lower percentage of older people living alone compared with their European neighbours.⁴

Specifically, in Spain, as per the data released by the National Statistics Institute in the 'Continuous Household Survey, 2017' there are 4687.4 billion people living in single-person households, representing 41.8% of all Spanish households. Furthermore, the number of men and women living in single-person households is different. Approximately 1.4 million single-person households are inhabited by women and around 0.6 million by men. In addition, the study provides data on cohabitation in old age, a situation that differs between men and women. Most men live with a partner (spouse, partner with or without children or others), representing 14.7% of men who live alone, while 29.3% of women live alone because of the early death of partner. In Spain, the total number of elderly persons living alone in their homes has reached 22.9%. This factor, in correlation with the health problems associated with ageing, the lack of a social support network and the feeling of loneliness could generate serious problems leading to a loss of well-being and drastic reduction in the quality of life self-perceived by the elderly person.⁵⁻⁷

In addition, as the population ages, there is an increased risk of cognitive impairment of varying intensity, which has a significant public health impact according to the WHO.⁸ Mild cognitive impairment (MCI) is described as a cognitive decline that is greater than expected for an individual's age and level of education, but does not significantly interfere with activities of daily living and therefore, does not require early institutionalisation. Patients with MCI have a higher risk of dementia compared with others in the same age group, but without cognitive decline, show gait disturbances (such as decreased walking speed) and a 50% greater risk of experiencing falls.⁹

Caregivers and families are also affected especially, when the patient with dementia is in a moderate or advanced phase. This overload is one of the main reasons for the institutionalisation of patients. Hence, we propose to use monitoring to reduce this load described in professional caregivers and families.

According to a report by the Spanish Society of Geriatrics and Gerontology, no studies have estimated the economic impact of International Marketing and

Communication, SA.¹⁰ Considering that MCI may be a pre-dementia stage, the direct and indirect economic burden will increase with the patient's age. Alzheimer's disease (AD) is the most common cause of dementia. The Organisation for Economic Cooperation and Development statistics showed that in 2018 there were 9.1 million patients over 60 years of age diagnosed with AD in the European Union (out of a total population of 513 million), and this number is expected to increase by 60% by 2040 reaching 14.3 million people with AD.¹¹ In addition, the health cost per patient is estimated to be around 20.000€ per year.¹² As for the USA, it is estimated that AD alone will affect more than 16 million people in 2050, at a cost of more than US\$1.1 billion.¹³

In Spain, the costs associated with cognitive impairment, dementia and AD in 2014 are estimated to be approximately €30 000 per patient. An important factor to be considered is that since 2010 the health costs associated with dementia have increased by 35% and this increase is mainly in the developed countries.¹⁴

Healthcare has long used advanced technological equipment to measure and better understand the patient's health status. In the past, researchers have focused on developing increasingly sensitive and accurate measurement devices for hospital use. The interpretation of results and diagnosis was left to expert physicians, who took the responsibility of decisions and treatment.¹⁵

However, the ongoing paradigm shift in healthcare requires refocusing care and moving it into a proactive and preventive perspective, looking for ways to keep people healthy by influencing their lifestyle and early detection of complications. The changes produced in recent years in the demand, management and financing of the health system were because of the circumstances that the system itself is going through to offer the established portfolio of services, its viability in the future and consequences and problems produced by the economic crisis. Hence, health professionals encouraged and educated patients to take control of their own healthcare process; thus, involving and empowering them. Over the years, it has been established that prevention only works when patients are actively involved in the process. The increasing amount of self-care and self-management of their own pathologies or disease processes has reduced hospital stays and frequent visits of the patients.

Demographic changes, including the ageing of society and consequent increase in the demand for healthcare, have made it essential for managers and professionals to seek alternatives and improvements in the efficiency of care provided at the individual and home level, always with a dual purpose: to reduce economic costs and increase the quality of services.^{16 17}

Technological advances have made these changes possible, as patients can now have solutions related to their health without the direct interference of medical staff.

Healthcare should benefit much more from proactive and discreet monitoring of healthy people and those most

at risk of illness (eg, older adults) through sensors built into their environment. This contributes to increased patient safety, early detection, prevention of illness, improved monitoring and treatment; therefore, reduced costs for the corresponding care provided.¹⁷

The urban lifestyle and advent of smart phones, mobility and immediate access to all information via the internet, including health information, has led to a totally disruptive change in most aspects of the daily life of the population with a certain degree of digital literacy. Hence, the health and welfare market has been subjected to a great impact. Customers are demanding an improvement in their quality of life and are willing to invest their resources in new technologies and consumer services that will generate an improvement in their daily lives.¹⁸

The potential and market niche for smart health products, solutions and services is substantial and growing rapidly and exponentially. Specific numbers detailing the size of the market or directly supporting growth expectations are not easy to calculate, as the quantitative data entering the field of smart health are rarely tracked or labelled as such in formal statistics. However, several calculations allow us to estimate the current size of the market and growth expectations in a generic way. Despite the difficulties associated with data availability, a study on the market deployment of internet of things solutions shows that the global smart health market is expected to grow by more than 19% annually.^{19 20} The much more expansive internet of people or internet of everything market, which in the near future, will include machine-to-machine, machine-to-person and person-to-person communications with almost infinite potential that cannot be ignored.²¹

The intelligent systems used for control and decision-making in healthcare are based on a variety of technologies that collect general and specific data through sensors and perform an in-depth analysis. The scans are performed by a combination of carefully chosen sensors, which probe various parameters, such as physiological parameters, habitual behaviour, activity level, location, among others. Perception sensors are specifically suited for this purpose, but their use is not common. Currently, in the field of healthcare, the most widely used devices for detecting and measuring variables, work by means of added cables, and clothing are considered as intelligent clothing because of their characteristics, performance and functionalities provided by the incorporated fabrics.

Currently, several technologies are available in the market that increase the sense of security and independence of the elderly. However, all these technologies cover only limited areas of the basic activities of daily life. Human functioning reflects a complex interaction between a person's health status and contextual factors. Therefore, a holistic view of daily activities using discreet surveillance technologies is needed, allowing for a long-term trend analysis of the routines of the elderly in the context of their individual life situation and environmental impact.²²

The practical implications of this review essentially aim to identify existing interventions that use technologies to determine their effectiveness for the detection, prevention, monitoring and treatment of patients at risk or diagnosed with MCI.

OBJECTIVE

The aim of this systematic review will be to evaluate the effectiveness of technology-based interventions in the detection, prevention, monitoring and treatment of patients at risk or diagnosed with MCI.

METHODS AND ANALYSIS

Design

The protocol for this review follows the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses for Protocols (PRISMA-P) reporting guidelines. The PRISMA tool will be used to conduct the intervention review.²³

Inclusion criteria

Participants

All studies that are conducted with persons aged 65 years or older who are at risk or diagnosed with MCI, and who are living independently in the community, alone, with family members or with caregivers will be included in this review; regardless of their sex, ethnicity, socio-economic or socio-cultural background.

Study design

Intervention studies will be included in the review, randomised clinical trials in any of their designs or pre-post non-randomised quasi-experimental designs, as these are the designs that are mostly used in the field of medical informatics.²⁴

Interventions

All the studies using information and communication technologies, such as pedometers, activity of daily living, such as exercise, heart rate or sleep monitoring, intelligent movement detection, devices or any other device or tool, to send, store and process information relevant to the prevention, detection, monitoring and treatment of patients at risk or diagnosed with MCI will be included in this systematic review.

Results

Articles will be included that provide relevant information on the use of technology and its effectiveness in interventions that assess improvements in relation to early detection, prevention and treatment of patients at risk or diagnosed with MCI.

Sources of information, management and data collection

The following databases: MEDLINE (PubMed), CENTRAL, CINAHL Plus, ISI Web of Science and Scopus

from 2010 to 2020, for the published articles in English and Spanish will be searched.

The search will be restricted to studies published between 2010 and 2020. The literature supports the premise that technology is advancing rapidly and that, therefore, including studies published before 2010 would yield obsolete results for our research objective.^{25 26}

We will additionally perform the following two actions to ensure that any relevant results are not missed: (1) A search on Google Scholar, considering the characteristics and shortcomings of the search engine in the systematisation of the syntax of the search strategy. (2) A manual search through the references of the most relevant studies. The search strategy for MEDLINE (PubMed) will be designed, following the recommendations of the Peer Review of Electronic Search Strategies statement.²⁷ Once the reviewers have reached a consensus, the strategy will be transferred to the aforementioned databases, adapting it to the particularities of each of the databases (syntax and proximity operators). The references obtained will be downloaded in the EndNote V.X9.2 reference manager software, which will also be used for the data deduplication process.²⁸

The initial search strategies proposed for MEDLINE (PubMed) and Scopus are presented in [tables 1 and 2](#), respectively.

Selection process of studies

The results obtained after the deduplication process will be exported to Covidence, a web-based literature manager software.²⁹ Through this platform, first, screening by title and abstract will be performed by two independent reviewers, according to the inclusion and exclusion criteria with the premises of relevant, irrelevant or doubt. At this stage the reviewers will explain the reason for exclusion of the article. When there is no consensus and in case of doubts, a third reviewer in discussion with the other two reviewers will make the decision. Once this screening by title and abstract is completed, the full texts of the articles will be searched, which will also be entered into the Covidence software. During the full-text screening, the reviewers will record the operationalisation of the variables in a codebook. Two investigators will independently review 25% of the randomly selected articles and 25% of the operationalisation of all variables written in the codebook. A third investigator will arbitrate in case of discrepancies. The results for each item will be checked to ensure that they are classified in the same category. Subsequently, the results will be analysed using the Kappa index formula through the IBM SPSS Statistics software (version 25), showing the level of agreement between the reviewers for included and excluded studies.

Evaluation of methodological quality and control of risk of bias

The studies included in the review will be analysed by the appropriate tools for their design. Thus, for randomised clinical trials, the Cochrane Reviews risk of bias 2 tool will

Table 1 PubMed search strategy

Concepts	PubMed search strategy	Search results
Technology	("Monitoring, Physiologic"[Mesh] OR Monitoring[tiab]) OR "Telemetry"[Mesh] OR Telemetr*[tiab] OR "Telemedicine" [Mesh] OR Telemedicine[tiab] OR "Mobile Health"[tiab] OR mHealth[tiab] OR Telehealth[tiab] OR eHealth[tiab] OR "Biomedical Technology"[Mesh] OR "Biomedical Technolog**"[tiab] OR "Health Technolog**"[tiab] OR "Health Care Technolog**"[tiab] OR "Therapeutic Technolog**"[tiab] OR "Monitoring, Ambulatory"[Mesh] OR "Artificial Intelligence"[Mesh] OR "Artificial Intelligence"[tiab] OR acceleromet*[tiab] OR pedometer[tiab] OR wearable*[tiab] OR smart[tiab] OR Sensor[tiab] OR "Self-Help Devices"[Mesh] OR "Self-Help Device**"[tiab] OR "Self Help Device**"[tiab] OR "Assistive Technolog**"[tiab] OR "Assitive Device**"[tiab] OR "Technology Screening"[tiab] OR "Technology-based screening"[tiab] OR "Technology based screening"[tiab] OR "Robotics"[Mesh:NoExp] OR "Social Robots"[tiab] OR "Robot-assisted"[tiab] OR "Socially-assisted robots"[tiab])	#1
Mild cognitive impairment	("Cognitive Dysfunction"[Mesh] OR "Cognitive Dysfunction**"[tiab] OR "Cognitive Decline**"[tiab] OR "Mental Deterioration**" OR "Mild Cognitive Impairment"[tiab] OR "Mild Cognitive Disorder"[tiab] OR "Mild Neurocognitive Impairment"[tiab] OR "Mild Neurocognitive Disorder"[tiab])	# 2
Total	# 1 AND # 2	# 3

be used to assess the risk of bias, and for pre-post non-randomised experimental studies, the checklist for quasi-experimental studies will be used. The PEDro scale³⁰ will be used to assess the methodological quality of pre-post non-randomised trials. The PEDro scale consists of 10 items that permit the evaluation of³⁰: (1) random allocation, (2) concealed allocation, (3) similarity at baseline, (4) subject blinding, (5) therapist blinding, (6) assessor blinding, (7) >85% follow-up for at least one key outcome, (8) intention-to-treat analysis, (9) between-group statistical comparison for at least one key outcome and (10) point and variability measures for at least one key outcome.

The certainty of the evidence will be rated according to the GRADE systematic approach. We will use the methodology proposed in the GRADE evidence profile table

Table 2 Scopus search strategy

Concepts	Scopus search strategy	Search results
Technology	TITLE-ABS-KEY (Monitoring OR Telemetr* OR Telemedicine OR “Mobile Health” OR mHealth OR Telehealth OR eHealth OR ((Biomedical OR Health OR Therapeutic OR Assistive OR Screening) W/3 (Technolog* OR Technology-Based OR “Technology based”)) OR “Artificial Intelligence” OR acceleromet* OR pedometer OR wearable* OR smart OR Sensor OR “Self-Help Device*” OR “Self Help Device*” OR “Assistive Technolog*” OR “Assitive Device*” OR “Social Robots” OR “Robot-assisted” OR “Socially-assisted robots”)	#1
Mild cognitive impairment	TITLE-ABS-KEY (“Cognitive Dysfunction*” OR “Cognitive Decline*” OR “Mental Deterioration*” OR “Mild Cognitive Impairment” OR “Mild Cognitive Disorder” OR “Mild Neurocognitive Impairment” OR “Mild Neurocognitive Disorder”)	# 2
Total	# 1 AND # 2	# 3

(new version) of the Handbook ‘manual grade: Grading of Recommendations Assessment, Development and Evaluation’ proposed by the GRADE working group.³¹

Data extraction and synthesis

The data to be extracted will be adapted according to the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions.³² The following data will be extracted: (1) Identification data of each of the studies: authors, title, country of publication, year of publication and funding of the study. (2) Data concerning the design of the study: design, intervention used, type of participants and technology used. (3) Data concerning the results: main results, limitations and conclusions. First, we will detect missing data and classify them into three categories: (1) completely random, (2) random and (3) non-random. To avoid loss of information, we will perform an estimation by imputing the missing data to each test arm expressing the degree of deviation, and replacing the data with predicted values from the collected data.³³

The extracted data will be peer reviewed, establishing a first pilot to check if the flow in the extracted information is correct.

Clinical heterogeneity of the studies included in this systematic review will be assessed by analysing similarity in participants, setting, interventions and outcome measures. The variability in study design and risk of bias will be examined to evaluate methodological

heterogeneity. The χ^2 test will be used to calculate the statistical heterogeneity, setting the level of significance at 0.05. In the presence of substantial heterogeneity (>80%) the pooling of studies will not be implemented.

Patient and public involvement

The data will be obtained from previously published research. Patients, public and private institutions and other entities are not involved in the development of the research question, outcome measures or study design. This research will not involve the participation of patients.

DISCUSSION

Ageing is an intrinsic reality that is marked by cellular ageing and genetic programming.³⁴ Human beings must face this scenario with a certain foresight and thus, be able to adapt correctly to the social, economic and health needs that appear throughout the process of ageing. Similarly, there are theories of social and psychosocial ageing reporting the changes that occur with the passage of time and the evolution of the individual.³⁵

However, we must look at this situation not only at the individual level, but also at the collective level. The increase in life expectancy in developed countries is causing their population pyramids to age, leading to a new reality that requires an exhaustive assessment and evaluation of future sociodemographic scenarios by experts in the field. People structure the different environments or spheres that surround them according to their needs and values, which can vary according to the moment in the life cycle where they are. The adaptation to the natural and constant changes that are conceived in the different stages of life, physical and psychic level, state of health, quality of life, family, social, religious and economic context will finally mark the needs that each individual can present and the support that they can have or need at the end of their life cycles.^{36 37}

Some researchers have performed interventions where they evaluated the effectiveness and use of new technologies in people over 65 years of age, although these interventions are not directly related to our study objective, since their inputs were directed to the reduction of loneliness, social isolation, chronic diseases and disabilities in general. These dissertations can support our study objective, as they showed promising efficacy. However, the authors emphasised the need for much more comprehensive intervention designs and evaluations.^{38 39}

Therefore, we considered the need to review the existing scientific literature on the use of technology in elderly people at risk or diagnosed with MCI. The main objective of our research is to improve the monitoring and treatment of patients at risk or diagnosed with MCI, to achieve a better prognosis through closer monitoring and application of early therapeutic strategies. Hernández *et al* conducted a cross-sectional descriptive correlation study where they collected and analysed data using technology and reported that through acoustic variables and

verbal fluency, early detection and monitoring of MCI could be achieved.⁴⁰

The results of this review will facilitate the identification of interventions where technology is used, for the detection, prevention, follow-up and treatment of patients at risk or diagnosed with MCI. Furthermore, this study will evaluate the methodological quality of the published research, which will enable to review and offer new perspectives of use of the sensorial technology in this specific health problem.

ETHICS AND DISSEMINATION

Ethics committee approval is not required for this protocol and subsequent systematic review. The main objective is to extract and summarise the results of studies that meet the inclusion criteria.

The results of the study and additional data will be disseminated through publications and participation in scientific conferences and workshops. A communication will be sent to the Healthio 2021.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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