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Telephone interventions, delivered by healthcare professionals, for educating and psychosocially supporting informal caregivers of adults with diagnosed illnesses

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

To evaluate the effectiveness of telephone interventions, delivered by healthcare professionals, when compared to usual care or non-telephone-based support interventions for educating and psychosocially supporting informal carers of people with acute and chronic diagnosed illnesses, on these carers’ quality of life, psychosocial and physical well-being. We aim, additionally, to evaluate the cost-effectiveness of telephone interventions.

BACKGROUND
Many people with diagnosed medical conditions are dependent upon family members and informal caregivers (that is a caregiver who is not paid (Levine 2010)), to provide support and care, usually in the home of the person needing care (Care Alliance Ireland 2015; International Alliance of Carer Organisations 2016). While the care provided varies according to individuals’ needs, with care categories defined as low, medium (instrumental care such as cooking and shopping), medium with personal assistance (such as washing and dressing) and high (Care Alliance Ireland 2015), in many instances informal carers find themselves in a caring role for which they are ill prepared (Smith 2004; Bauer 2009; Nalder 2012; Levine 2013; Coleman 2015). Providing care may impact negatively on the caregiver from an emotional, physical, social and financial perspective (Glendinning 2009; Care Alliance Ireland 2010; OECD 2011). Internationally, the focus of healthcare is to have people cared for in the community as long as is possible. The aim is to shift to community-based and patient-centred paradigms of care for the treatment of chronic diseases (WHO 2006); and, where possible, prevent admission to secondary healthcare facilities. Unpaid or informal caregivers have been described as the backbone of the healthcare system (Wolff 2006; Levine 2010; Care Action Network 2013; OECD 2013); and worldwide they play a key role in the provision of care, saving billions in healthcare expenditure (Navine-Waliser 2002; Levine 2010).
Description of the condition

The international literature suggests that caregiving impacts similarly on caregivers irrespective of geographical location or of the illness being experienced by the care recipient. In a UK study, Golics 2013 reported that caregivers caring for family members with a range of illnesses experienced worry, frustration, anger and guilt. For some, adjustment to the role is difficult and requires significant emotional and life changes. This is reflected across the world with national studies from Japan (Oshio 2015), South Korea (Do 2015) and Canada (Penning 2015) highlighting the negative effects of caregiving on specific groups of informal caregivers. Family members providing unpaid care have been described "...as a hidden "patient" group..." (Golics 2013, p795). The need for professional support for caregivers has been reported and highlighted across a range of acute (i.e. time-bound and responsive to treatment) and chronic (i.e. not time-bound, non-curable and susceptible to remission and exacerbation) conditions (Murrow 1996). This includes support for caregivers of people surviving complex illness (Czerwonka 2015), patients with cancers (Janda 2006; Braun 2007; Guldin 2012; Heese 2013; Merckaert 2013; Mosher 2013), chronic and terminal illnesses (Riess-Sherwood 2002), mental health problems (Gavois 2006), stroke (Cameron 2013), Parkinson’s disease (Oguz 2013), dementia (Peeters 2010; Lilly 2012; Van Mierlo 2012; Zwaanswijk 2013), multiple sclerosis (Corry 2009), and family caregivers who are new to the role (Plank 2012). Golics 2013 argues that having access to people with the knowledge and skill to provide support, in particular emotional support, may ease the burden of caring. Although the impact of caregiving may be similar, how it is experienced by caregivers differs. Within caregiver groups such as caregivers of older persons (Unson 2016) and people with schizophrenia (Roick 2007), researchers have noted that gender, relationship to patient, level of contact with the patient (Roick 2007; Unson 2016), solo caregiver status, younger age (Unson 2016) and unemployment (Roick 2007) all influence how caregivers experience burden. McCabe 2009 further reports lower mood and quality of life in caregivers of people with motor neurone disease and Huntington’s disease compared to caregivers of people with Parkinson’s disease and multiple sclerosis. Adjusting to the role of caregiver has been described as a non-linear or oscillating process (Robinson 2005; Greenwood 2010) that is continual (O’Shaughnessy 2010), gradual and occurs over time (Robinson 2005; Hasson 2010). The process of adjustment differs for caregivers within and across conditions (Pakenham 2001; Pinquart 2003; Heru 2004; Smith 2004; Davidson 2012; Cameron 2016) and results in significant emotional and life changes, particularly in the first year (Elliott 2001). For some, burden and anxiety levels decrease over time (Elliott 2001; Davidson 2012), with significant reductions found within a year (Smith 2004; McCullagh 2005), though decreases are less likely if caregivers have poor health (Savage 2004; Cameron 2016).

Description of the intervention

Healthcare professionals commonly communicate with care recipients and their family members by telephone. A number of research studies have evaluated use of the telephone only (Hartke 2003; Bakas 2009; Van Mierlo 2012), or the telephone as a component of an intervention (Brown 1999; Mahoney 2003; Walsh 2003; Chang 2004; Bank 2006; Smith 2006; Glueckauf 2007; Rivera 2008; Sepulveda 2008; Tromont 2008; Borman 2009; Van Mierlo 2012; Pjamjariyakul 2013). Some of the interventions are delivered by healthcare professionals and others are delivered by peers (Goodman 1990), or co-facilitated by befriending volunteers (Charlesworth 2008). In this review, the focus will be on evaluating the telephone only, as a support intervention, delivered by healthcare professionals for caregivers of people with acute and chronic conditions. In this review, a telephone intervention is defined as an intervention that enables healthcare professionals to verbally communicate remotely with caregivers. A healthcare professional is a trained healthcare person who has received specific healthcare education and training in the management and care of people with diagnosed conditions, their family members, significant others or caregivers (e.g. nurses, medical doctors, social workers, physiotherapists, occupational therapists, counsellors/psychologists and dieticians/nutritionists).

How the intervention might work

Professional support

Healthcare professionals provide services to patients and families/caregivers within the scope of their professional practice (Hucpey 1997). This includes direct care to people with diagnosed illnesses and indirect care, in the form of supportive advice, professional information and psychosocial/educational support to carers of people with diagnosed illnesses. In general, the benefits of professional support are likely to be dependent on the issues being addressed (Rosland 2008), and the readiness and receptivity of the person receiving the support (Toseland 1989; Hogan 2002). Reinhard 2008 demonstrated that professional support selectively reduces caregiver burden for those caring for people with mental health problems. Specific types of professional support such as practical advice in managing behaviours were found to be helpful in reducing objective burden (family arguments, missing days at work, household disruptions) (Reinhard 2008). Deek 2016 also reported favourably on family-centred self-care interventions, delivered by trained personnel, for adults living with chronic conditions and concluded that appropriate education and support should be provided by healthcare professionals (Deek 2016). Professionals have the education and training to provide emotional support to caregivers, helping ease the social isolation and emotional demands of caregiving (Mittelman 1996). A number of strategies, as de-
scribed below, that aim to improve caregiver outcomes are within the scope of the ‘support’ role of healthcare professionals.

**Strategies to improve caregiver outcomes**

Caregiver support programmes help promote caregiver health by providing psychological support, information and education to caregivers, while taking cognisance of caregivers’ limited time and resources (Gendron 2013). These psychoeducational programmes help carers develop skills in identifying signs of distress, managing symptoms, coping strategies/skills, and provide help with finding and accessing social support services (Riess-Sherwood 2002). The telephone has been described as a good means of exchanging information, providing health education and advice, managing symptoms, recognising complications early, giving reassurance and providing quality service (Thompson 2007).

Strategies to improve caregiver outcomes include providing education or information, assisting carers with problem solving, learning coping skills/behaviours, effective use of resources, seeking out social support and identification of signs of distress (Riess-Sherwood 2002). Coping strategies have been effective in improving the psychological health of caregivers of people with dementia (Selwood 2007). Likewise preparedness to care was found to reduce caregiver burden for caregivers of older persons (Zwicker 2010), and those with cancer (Scherbring 2002; Zwicker 2010). It was also found to ameliorate some aspects of role strain (Archbold 1990), and was the strongest predictor for lowering caregiver stress in stroke caregivers (Ostwald 2009). Failure to help caregivers master the skills and ability to manage their own health and well-being during the early phases of caregiving may lead to greater difficulty integrating strategies, such as coping strategies, into daily life in later stages of the caregiving process (Riess-Sherwood 2002). All of these strategies are amenable to delivery/initiation via the telephone. Reinhard 2008 contends that “...even a simple one-to-one telephone call may be effective in helping the caregiver...” (p345). In this review, any strategy involving educational and psychosocial support strategies, or a combination of these, that focus on caregiver quality of life, burden, skill acquisition, psychological health, knowledge and understanding, health status and well-being, family functioning and satisfaction will be considered (see ‘Types of outcome measures’ for further detail).

**Factors that help overcome barriers to supporting caregivers**

When distance, inconvenience, being homebound or reluctance to leave the care recipient hinder face-to-face interventions (Hartke 2003), telecommunications and other media can be used (Badr 2016). Wilz 2016 concludes that the telephone is highly acceptable to family carers and reports on two qualitative studies which indicate that such interventions may meet carers’ needs in respect of information, guidance, professional and emotional support. Badr 2016 also suggests that telecommunications and other media interventions will enable carers to manage their own feelings and promote their ability to care. These findings support earlier qualitative research which reported that telephone support was a convenient and trouble-free means of providing support to caregivers of people with dementia (Salifi 2005).

**Reported benefits of telephone support interventions for caregivers**

Previous research indicates that caregiver telephone interventions lead to positive outcomes (Topo 2009; Chi 2015). In a systematic review of telehealth tools and interventions to support caregivers, 20 of the 65 included studies reported on telephone-based interventions (Chi 2015). Detailed results from individual telephone-based studies are not reported in the review. Collective summary findings of all technology-based interventions, such as videoconferencing, telemetry and remote monitoring are presented, with the authors of the review stating that 62 of the 65 included studies (95%) reported that caregivers had significantly improved outcomes (Chi 2015). Dam 2016 reported mixed findings from telephone interventions for caregivers of people with dementia, but further analysis of the included studies revealed that various research designs - including the ‘pre-test post-test’ design - were used, and in some instances the telephone was only a component of the intervention upon which the conclusions were formed. The benefits of any intervention is dependent on timing, readiness of recipient and the nature of the issues that need to be addressed. Research indicates that support may only be effective when the recipient perceives a need for the support (Melrose 2015). In this sense, the appropriateness of professional support is likely to be dependent on the required effects. Although we could not find any studies that explicitly explored the differences between the effectiveness of professional and peer support for caregivers, a study by Rosland 2008 found that support from family and friends impacted on different self-management behaviours for people with diabetes to those impacted upon by professionals. This suggests that for some self-management behaviours family support may be required; but professional support is more appropriate for others and that the type of support offered should be guided by the desired outcomes. In general professionals are more likely than non-professionals to affect outcomes that require therapeutic intervention (e.g. psychological functioning and personal change), while
non-professionals are more likely to positively change participation in informal social support networks (Toseland 1989).

**Why it is important to do this review**

There is a lack of international information and evidence on carers (OECD 2011). The number of caregivers varies according to overall population with figures varying from 60,000 in Finland to 43.5 million in the USA (International Alliance of Carer Organisations 2016). It is estimated that across the Organisation for Economic Co-Operation and Development (OECD) countries more than 1 in 10 adults provide informal care. Across the European Union (EU) 19 million people provide care of which 9.6 million provide at least 35 hours’ care a week (Glendinning 2009). This number is expected to grow by 2030 (Glendinning 2009). While the financial contribution of informal caregivers to international reduction in healthcare expenditure is unknown, it is estimated that informal caregivers contribute an annual estimated national reduction in healthcare expenditure varying from EUR 20 billion in Sweden to USD 470 billion in the USA (International Alliance of Carer Organisations 2016). This is likely to reflect the contribution of estimated care hours provided by informal carers. The contribution of family members is being increasingly recognised as important to the provision and management of care in chronic illness (Rosland 2010), and across the spectrum of illnesses (Coleman 2015; Haines 2015). However, uptake of the support provided may not be feasible for caregivers due to geographical location, time and cost. A report on a survey of eight European countries highlights that, while the availability of support for caregivers of people with dementia was high, uptake was low, and utilisation may depend on the degree of accessibility of the support and caregivers’ ability to perceive, seek, reach out, pay and engage with the services (Lethin 2016). The telephone provides a mode of intervention delivery that has the potential to increase accessibility and affordability of support programmes.

**Distribution of caregivers and telephone availability**

As caregivers live in the community, are regionally and nationally dispersed, and are often in paid employment in addition to their unpaid caregiving role (OECD 2011; International Alliance of Carer Organisations 2016), face-to-face contact with people who can provide emotional support and advice is not always feasible. Attendance-based interventions can be time-consuming and expensive for the caregiver (Kaltenbaugh 2015; Ravenson 2016). Telephone communication is widely available, internationally, with almost everyone having some form of access to a telephone including individuals living in remote settings (Lavender 2013). Pew Research Centre 2015 reported a median of 84% mobile phone ownership in emerging and developing countries with mobile phone ownership rates ranging from 47% to 97% in Pakistan and China, respectively. In 2011, of the 5.3 billion users of mobile phones worldwide, 3.5 billion were from developing countries (Shozi 2013), and it is projected that 70% of the world population will use smartphones by 2020 (Williams 2015), which will equate to more than 6.1 billion users (Lunden 2015). However, 10% of the world’s population do not have access to mobile phones, with the majority of these from the rural areas of Asia and sub-Saharan Africa (Consumer Technology Association 2015). Seventeen percent of people in sub-Saharan Africa do not own a mobile phone but more than half of those people have, at times, access to a fixed line phone (Pew Research Centre 2015). Despite this, the mobile market growth rate in sub-Saharan Africa is one of the highest worldwide (Deloitte 2012); and the growth in mobile phone networks has transformed communications in sub-Saharan Africa, an area with the highest disease burden (Vos 2015).

**Feasibility of technology-based interventions**

Research studies, in particular studies in stroke, dementia, and human immunodeficiency virus, indicate that technology-based interventions can be feasibly implemented for caregivers of people with many different conditions (Herman 2006; Brereton 2007). Integrating telephone/mobile technology into current healthcare strategies provides a potential means for new ways for healthcare professionals to deliver care to patients and their caregivers (Deloitte 2014). Finkel 2007 argues that “…technology offers a cost effective and practical method for delivering interventions to caregivers” (p443). Despite this assertion, there is little evidence currently of economic advantage (an aspect that we will explore in the review) other than the suggestion that the need for healthcare professionals and caregivers to travel is eliminated, and caregiver access to existing resources and programmes is enhanced (Finkel 2007).

**Factors that mitigate against implementation of findings to date**

A number of factors mitigate against the usefulness of the findings from existing literature reviews and individual studies that included a telephone component. These include failure to present findings for different components of the interventions, failure to explore the benefits or otherwise of group over individual telephone interventions or to examine the essential characteristics of the interventionists. For example, in a literature review on technology studies to meet the needs of people with dementia and their caregivers, in which 15 of the included papers focused on caregiver interventions (Topo 2009), most of the interventions were complex interventions with the telephone as one component. As outcomes from the specific components of the intervention were not isolated or presented individually, the benefit of the telephone alone was difficult to determine. Failure to isolate/present findings from individual components of a multi-component intervention
can limit the application of such interventions. This may occur due to limited resources, including funds, if all elements of the intervention are essential to effect outcomes. If the benefits from a multi-component intervention could be realised with the application of any one component of the intervention, this needs to be highlighted so that healthcare resources are applied in an efficient and effective manner. Likewise the potential benefits of telephone-only support interventions, delivered by healthcare professionals to individuals or groups, needs to be established. There is little empirical evidence to support the effectiveness of group interventions over interventions delivered to participants individually (Toseland 1989). While studies evaluate the effects of different modes of delivering interventions to groups, e.g. telephone versus face-to-face, we were unable to find any studies that tested the effects of a telephone group versus telephone one-to-one approach to intervention delivery, although these may be conducted in the future. No Cochrane review was found that focused on telephone interventions for informal caregivers across a range of medical conditions. We found one Cochrane review that used the telephone for delivering a counselling intervention by healthcare professionals to caregivers of people with dementia only (Lins 2014). In a meta-analysis of three trials in this review, depressive symptoms from telephone counselling alone were reduced and potential positive effects of other outcomes including distress, burden, anxiety, quality of life, self-efficacy, satisfaction and social support, were also suggested. While the studies included in Lins 2014 are likely to be included in this review, they will be analysed along with telephone support interventions for a range of conditions, so improving our knowledge on the telephone’s effectiveness as a means of delivering psychosocial support or education to caregivers of people across a broad spectrum of conditions. This Cochrane review differs from other Cochrane reviews on caregiver interventions (Ellis 2010; Chan 2011; Legg 2011; Vernooij-Dassen 2011; Aubin 2012; Forster 2012), as, unlike these reviews, the main objective of our review is to determine whether or not the telephone alone as a mode of delivering a support intervention to caregivers of diagnosed illnesses is effective. Other Cochrane reviews that differ from our review include those by Candy 2011 and Lavender 2013. Candy 2011, who evaluated peer-support interventions for caregivers, did not report any findings specific to the telephone. Lavender 2013 concluded that there was insufficient evidence to recommend routine telephone support for women accessing maternity services.

A number of the reviews on caregiver interventions that included telephone interventions did not differentiate between telephone-only interventions and interventions that included the telephone as a component of the intervention. For example, Forster 2012 included one study that targeted patients and another that was a hybrid intervention that included two home visits and two telephone contacts. Similarly only one included study in the Legg 2011 review was telephone only; the other included study consisted of a combination of face-to-face and telephone intervention delivery. In the review by Candy 2011, none of the three included studies used the telephone as the only method of intervention delivery. One telephone-only intervention was included in the review by Vernooij-Dassen 2011 but the telephone was used as the comparator intervention for two of the other included studies.

Two Cochrane protocols where telephone interventions are likely to be included as part of the review were identified (Santin 2012; González-Fraile 2015). González-Fraile 2015 focuses on the provision of information, support and training for informal caregivers of people with dementia and indicates that the telephone is a potential format for administering the intervention. Santin 2012 focuses on psychosocial interventions for informal caregivers of people living with cancer, stating that interventions that include telephone counselling will be included. Although there may be some overlap between these two reviews and our review, the overall scope of this review is broader and has a specific focus on the telephone only as the mode of intervention delivery across a range of conditions.

In summary, the need for professional support for caregivers across a range of conditions is well established. As difficulties for caregivers attending face-to-face interventions have been highlighted (Badr 2016; Wilz 2016), telephone-based interventions across caregiver groups provide a potentially important alternative. To date, there is no Cochrane review on the effectiveness of telephone support interventions alone, delivered by healthcare professionals, for caregivers across a range of conditions. It is therefore important to determine whether or not support interventions delivered by telephone are effective so that healthcare professionals can make informed decisions about whether or how to use the telephone in providing support to caregivers, should it be shown to be effective. Consequently, this review sets out to determine the effectiveness of educational or psychosocial support interventions, or both, delivered exclusively by telephone and by healthcare professionals, for informal caregivers of people with acute and chronic illness. The results of this review have the potential to inform strategy on the use of the telephone as an easily accessible, low-cost method to provide high-quality care with the potential to benefit hundreds of thousands of informal caregivers worldwide. It can also contribute to the primary care agenda by delivering healthcare to caregivers and patients in remote and rural areas. In addition, the findings will assist with research, resource allocation and future planning for the promotion and optimisation of the health and well-being of informal caregivers.

**Objectives**

To evaluate the effectiveness of telephone interventions, delivered by healthcare professionals, when compared to usual care or non-telephone-based support interventions for educating and psychosocially supporting informal carers of people with acute and
chronic diagnosed illnesses, on these carers’ quality of life, psychosocial and physical well-being. We aim, additionally, to evaluate the cost-effectiveness of telephone interventions.

METHODS

Criteria for considering studies for this review

Types of studies
We will include randomised controlled trials (RCTs) (including cluster-RCTs) and quasi-RCTs. We will include multi-arm studies that include a pair-wise comparison of intervention groups that otherwise meet the inclusion criteria for this review (Higgins 2011a), and where data specific to the telephone component of the intervention can be extracted in isolation. We will exclude cross-over trials as there is a high risk of carry-over effects from one intervention to another (Higgins 2011a).

Types of participants
We will include informal adult caregivers, defined as persons aged 18 years or over, caring for adult individuals with a diagnosed illness and in receipt of telephone intervention support from a healthcare professional. For the purpose of this review a caregiver is defined as a person (family member, friend or significant other) who provides personal help (support or care) for a person with an acute or chronic illness, and is not a paid healthcare provider. An acute illness is defined as a diagnosed condition lasting less than six months and a chronic illness is defined as a diagnosed condition lasting for six months or more.

We will include telephone interventions delivered by healthcare professionals to caregivers of people with a range of diagnosed illnesses who are living in a hospital, residential care or in the community. The following provides an indicative list of examples, based on author familiarity with the subject area and referenced sources, as available. The examples within the condition categories are also intended to be illustrative rather than exhaustive.

- Complex critical illness survivors (i.e. people who need caregivers on the path to recover from the intensive care unit to the home environment).
- Mental health: severe mental illnesses (e.g. schizophrenia, depression, bipolar affective disorders) (Vermeulen 2015).
- Neurological conditions (e.g. dementia, epilepsy, multiple sclerosis, Parkinson's disease, stroke, traumatic brain injuries, Huntington's disease, headache disorders, neuro infections, pain associated with neurological disorders) (WHO 2006).
- Respiratory conditions (e.g. asthma, chronic obstructive Airways disease).
- Cardiac conditions (e.g. congestive heart failure, myocardial infarction).
- Renal conditions (e.g. renal failure).
- Orthopaedic conditions (e.g. hip fractures, spinal injuries).
- Musculoskeletal (e.g. degenerative osteoarthritis).
- Infections (e.g. HIV/AIDS).
- Haematological conditions (e.g. post bone marrow transplant).
- Endocrine: (e.g. diabetes 1 and 2).
- Alcohol, drug or substances issues/misuse.
- Cancer: any category.
- Terminal illness: due to any of the above conditions.
- Older persons: frail older persons or older persons with any of the above conditions.
- People with comorbidity or multimorbidity.

Types of interventions
We will include all telephone interventions delivered by healthcare professionals that provide education or psychosocial support or a combination of these for informal caregivers. Telephone interventions where the first session is an introductory session either delivered by telephone or face to face and where all remaining sessions are delivered by telephone will be included. Accordingly, we will exclude all caregiver interventions that are not telephone based, telephone interventions delivered by non-healthcare professionals and telephone interventions targeted towards paid caregivers, patients, people living in the community who are not informal caregivers and healthcare professionals. Neither will we include interventions that include the telephone as a component of a multi-component intervention where the findings for the telephone component of the interventions cannot be isolated. Telephone interventions with more than one face-to-face session or where the first face-to-face session follows an overall introductory session to the intervention will also be excluded.

We will include trials that compare a telephone support intervention delivered by a healthcare professional with either ‘usual’ care (as defined by the study’s authors), or a support intervention delivered by a healthcare professional that is not telephone based, analysing these comparisons separately. The included intervention will be categorised as either an educational or psychosocial intervention, or a combination of both. Psychosocial interventions refers to the cognitive, behavioural and/or social mechanisms of action, e.g. counselling, psycho-education, behavioural and cognitive intervention and social support, that aim to improve the psychosocial and physical well-being of carers of people with chronic conditions. Psychosocial intervention will therefore be further categorised as counselling interventions, psycho-educational, social support, behavioural or cognitive training interventions. Educational interventions, which often include information provision, are often more difficult to pin down and define. For the purposes of this review, we will categorise an educational inter-
intervention as one in which information is provided for the purpose of increasing the carer's factual knowledge, as well as interventions that include a component that ensures that the carer understands the information given and can put it into action (Mahan 1963), and/or where the intervention has been defined/described as an educational intervention by the trial/study authors. The following operational definitions will be used to identify papers for inclusion in our review:

- For the purposes of the review, a healthcare professional is defined as a registered healthcare practitioner, who may or may not be a member of the wider clinical team, who has received an education/training qualification and who provides telephone education and psychosocial support to caregivers. This includes nurses, social workers, medical doctors, counsellors, psychologists and other related allied healthcare professionals.

- For the purposes of the review, a telephone intervention refers to any intervention, delivered via the telephone, with an education or psychosocial (mental, emotional, social or spiritual) focus that is designed to provide knowledge, advice, or help to caregivers in order to enable them manage their own well-being or that of the person they care for. This support can be provided individually or in group format. For the purpose of this review, telephone interventions include calls from any device that enables audio communication between healthcare professionals and caregivers, including calls made using landlines, mobile phone devices and devices that enable the use of Skype or other applications that facilitate verbal communication between healthcare professionals and caregivers. Telehealth interventions that provide online education or interventions other than telephone calls between healthcare professionals and caregivers will be excluded.

Types of outcome measures

The following outcomes will be assessed at several time points, reflecting the possible changes in caregiver outcomes over time. All outcomes will be assessed at the end of intervention delivery and at short-term (≤ 3 months), medium-term (> 3 to ≤ 6 months) and longer-term time points (> 6 to 12 months) following intervention delivery.

Primary outcomes

- Caregiver quality of life (QoL) as measured by the trial/study authors or using a measurement instrument (e.g. SF 36, WHOQoL or caregiver QoL index).
- Caregiver burden as measured by the trial/study authors or using a measurement instrument (e.g. caregiver reaction assessment, carer burden inventory or caregiver strain index).

Secondary outcomes

The following secondary outcomes will be measured.

- Skill acquisition (preparedness to care; caregiver competence, problem solving, social activity).
- Psychological health (depression, anxiety, stress, coping).
- Knowledge and understanding (knowledge).
- Health status and well-being (physical health, self-efficacy).
- Family functioning.
- Satisfaction: (satisfaction with the intervention, perceived satisfaction with practical or other supports).
- Economic outcome data as reported from cost benefit analysis, cost-effectiveness analysis, cost utility analysis.

Unintended outcomes that could be attributed to the intervention will be considered adverse events. These include any worsening of the above outcomes in the intervention group, as reported by the study authors or as evident in worsening of end of treatment from baseline (pre-intervention) measurement, where provided in the included studies, in particular anxiety and depression. Reported incidents of suicide ideation and suicide will also be considered adverse events.

Outcomes reported in included studies will be categorised to the groupings above by two authors working independently, with any differences in categorisation resolved by involvement of a third author.

We plan to report results for the following outcomes in ‘Summary of findings’ tables in the review:

- Caregiver quality of life.
- Caregiver burden.
- Psychological health (depression, anxiety, stress, coping).
- Satisfaction (satisfaction with the intervention).
- Suicide ideation and suicide.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases using a combination of appropriate key words and MeSH terms.

- The Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library (latest issue).
- MEDLINE OvidSP (inception to search date).
- Embase OvidSP (inception to search date).
- PsycINFO OvidSP (inception to search date).
- ProQuest Dissertations and Theses (inception to search date).
- CINAHL (Ebsco).

We present the strategy for MEDLINE OvidSP in Appendix 1. We will tailor strategies to other databases and report them in the review. There will be no language or date restrictions.
Searching other resources

To identify any further potentially eligible studies that might not be captured in our search of the electronic database, we will search also the grey literature database of OpenSIGLE (Systems for Information on Grey Literature in Europe) (www.opengrey.eu/) and the metaRegister of Controlled Trials (www isrctn com/page/mrct) for ongoing and recently completed studies. We will contact experts in the field and authors of included studies for advice as to other relevant studies.

Data collection and analysis

Selection of studies

All database search results will be merged using reference management software EndNote and duplicates will be removed. Two pairs of two review authors (MC, KN and MC, SB) will screen the titles and abstracts identified from searches to determine those that meet the inclusion criteria. Each pair will independently screen half of the selected titles and abstracts, with MC involved in the screening across the two pairs. We will retrieve in-full text of any papers identified as potentially relevant by at least one author. The same pairs of authors will independently screen full-text articles for inclusion or exclusion, with discrepancies resolved by discussion and by consulting a third author (VS) if necessary, to reach consensus. Studies will not be excluded on the basis of non-measurement/reporting of reviews’ pre-specified outcomes, where all other inclusion criteria are fulfilled. We will list all potentially relevant papers excluded from the review at this stage as ‘excluded studies’, and will provide reasons in the ‘Characteristics of excluded studies’ table. We will also provide citation details and any available information about ongoing studies, and collate and report details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review. We will report the screening and selection process in an adapted PRISMA flow chart (Moher 2009).

Data extraction and management

The same pairs of review authors will extract data independently from included studies. Clear decision rules based on participants, interventions, comparators and outcomes will be developed to assist the reviewers prior to commencing data extraction. Any discrepancies will be resolved by discussion until consensus is reached, or through consultation with a third author (VS) where necessary. If disagreements are still unresolved the study authors will be contacted for study details that may lead to a resolution of the disagreement. Unresolved disagreements will be reported in the review. The process will be recorded by maintaining separate electronic copies of the original data as extracted and a separate copy of the consensus data.

We will develop and pilot a data extraction form using the Cochrane Consumers and Communication Review Group Data Extraction Template (available at: cccrg.cochrane.org/authors resources). We will extract the following data: aim of study, study design, intervention type, comparison, number of participants, ethical approval, risk of bias, outcomes of interest, data and results, and funding sources.

In accordance with the recommendations of Herbert 2005 we will note and record any reported quality descriptions or rating by the study authors. We will evaluate and modify Section 5 of the data extraction form to ensure that we extract data that will allow us to evaluate the quality of the intervention in terms of the framework used to develop the intervention, stated aim/goal of the intervention, match between intervention and stated goal, intensity of the intervention in terms of frequency of delivery/receipt (weekly, bi-weekly, two weekly, monthly) and duration (in months), and fidelity to the intervention in terms of the extent to which it was delivered in a consistent manner (Bellg 2004; Mars 2013), and in accordance with the intervention trial protocol (Gearing 2011; Mars 2013). The extent to which contamination was minimised and monitored, the selection and standardisation of training the interventionists, standardisation and monitoring the delivery of the intervention, monitoring receipt of the intervention and the ability of participants to use the skills are all important aspects of fidelity which will be evaluated (Bellg 2004; Resnick 2005; Mars 2013). We will devise and pilot a quality-assessment instrument based on Section 5 of the data extraction form, which will enable us to categorise the interventions as low, medium or high quality based on the extent to which it was developed and delivered in accordance with best practice guidelines (Bellg 2004; MRC 2008; Corry 2010; Gearing 2011; Mars 2013).

One review author (MC) will enter all extracted data into Review Manager 5 (RevMan 2014), and a second review author (VS) working independently, will check it for accuracy against the data extraction sheets.

Assessment of risk of bias in included studies

We will assess and report on the methodological risk of bias of included studies in accordance with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011b) and the guidelines of the Cochrane Consumers and Communication Group (Ryan 2013), which recommend the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data; selective outcome reporting; and other sources of bias such as unbalanced groups and risk of contamination. We will consider blind-
ing separately for different outcomes where appropriate (for example, blinding may have the potential to affect differently subjective versus objective outcome measures). We will judge each item as being at high, low or unclear risk of bias as set out in the criteria provided by Higgins 2011b, and provide a quote from the study report and a justification for our judgement for each item in the 'Risk of bias' table.

Studies will be deemed to be at the highest risk of bias if they are scored at high or unclear risk of bias on both sequence generation and allocation concealment and high or unclear on either risk of contamination, selective outcome reporting or attrition bias domains, based on growing empirical evidence that these factors are particularly important potential sources of bias (Higgins 2011b). Blinding is not always possible at the point of intervention delivery and receipt due to the nature of the intervention, and for this reason has not been considered for assessment for high risk of bias in this review.

In all cases, two authors (MC and KN or MC and SB) will independently assess the risk of bias of included studies, with any disagreements resolved by discussion to reach consensus. We will contact study authors for additional information about the included studies, or for clarification of the study methods, as required. We will incorporate the results of the risk of bias assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment of the risk of bias of included studies and a judgement about the internal validity of the review’s results. If quasi-RCTs are included in the review we will assess and report quasi-RCTs as being at a high risk of bias on the random sequence generation item of the ‘Risk of bias’ tool. If cluster-RCTs are included in the review we will assess and report the risk of bias associated with an additional domain: selective recruitment of cluster participants. If multi-arm trials are included we will assess risk of bias in the reporting of outcomes. If outcomes are not reported for each arm of the trial separately in multi-arm trials, we will evaluate the risk of selective reporting of comparisons of intervention arms. If studies have different risk of bias we will use multiple analysis and present an estimate for studies at low risk of bias and one from all studies, which will include studies with unclear and high risk of bias as recommended by Higgins 2011b.

**Measures of treatment effect**

For dichotomous outcomes such as those that may be reported on the Caregiver Strain Index (CSI)/Caregiver burden scale (CBS-M), we will analyse data based on the number of events and the number of people assessed in the intervention and comparison groups. We will use these to calculate the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we will analyse data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI. If the MD is reported without individual group data, we will use this to report the study results. If more than one study measures the same outcome using different tools, we will calculate the standardised mean difference (SMD) and 95% CI using the inverse variance method in RevMan 2014.

Where a study reports on more than one outcome from an outcome category, and the outcomes will be included in a meta-analysis, we will select the outcome that the study authors have identified as being their primary outcome. Where no primary outcome has been identified, we will select the one specified in the sample size calculation. If there are no sample size calculations, we will rank the effect estimates of the outcomes (as presented in the study’s results) and select the median effect estimate. Where there is an even number of outcomes, the outcome whose effect estimate is ranked n/2, where n is the number of outcomes, will be selected. We will report results at different follow-up times: short term (completion of the intervention to ≤ 3 months), medium term (> 3 to ≤ 6 months) and long term (> 6 to 12 months).

**Unit of analysis issues**

For multi-arm trials we will extract data from comparisons relevant to our review i.e. we will extract data from study arms that compare the effects of telephone-only interventions delivered by healthcare professionals to usual care or a support intervention delivered by healthcare professionals that is not telephone-based for persons with diagnosed acute illness who are living in a hospital, residential care or the community. To avoid a unit-of-analysis error, in accordance with Higgins 2011b guidelines, in multi-arm trials we will combine groups to create a single pair-wise comparison. Where an intervention is analysed separately with different comparators the number of participants in the comparator group will be divided appropriately, prior to analysis (i.e. by half if two control groups, by a third if three comparator groups and so on). If cluster-RCTs are included we will check for unit-of-analysis errors. If errors are found, and sufficient information is available, we will re-analyse the data using the appropriate unit of analysis, by taking account of the intracluster correlation (ICC). We will obtain estimates of the ICC by contacting authors of included studies, or impute them using estimates from external sources. If it is not possible to obtain sufficient information to re-analyse the data we will report effect estimates and annotate unit-of-analysis error. If necessary we will seek further expert statistical advice when analysing data from cluster trials.

**Dealing with missing data**

We will attempt to contact study authors to obtain missing data (participant, outcome, or summary data). For participant data, we will, where possible, conduct analyses on an intention-to-treat basis; otherwise data will be analysed as reported and noted as a potential source of bias in our ‘Risk of bias’ assessments. Studies
of telephone interventions for caregivers are likely to have high loss to follow-up, with attrition rates of up to 45% reported in intervention groups (Tremont 2008) and 65% for control groups (Glueckauf 2007). We will report on the levels of loss to follow-up and assess this as a source of potential bias where more than 40% loss to follow-up on primary outcomes will be considered high risk of bias. Following attempts to contact study authors, where we fail to obtain missing outcome data the denominator for each outcome in each trial will be the number randomised minus any participants whose outcomes are known to be missing; that is we will use the numbers reported in the study. For continuous data, where measures of central tendency and variance - for example medians and standard errors - are sufficiently provided in a study report, we will convert these to means and SDs where possible, using the appropriate formulae, and input accordingly. If means only are available, we will use the SD from other studies in the review for the same outcome (Higgins 2008).

Assessment of heterogeneity
The studies will be grouped in terms of outcomes and, following main outcome analysis, will be further sub-grouped in terms of telephone intervention type (education or psychosocial support or a combination of both), outcomes (short-term completion of the intervention to ≤ 3 months, medium term > 3 to ≤ 6 months and long term > 6 to 12 months) and intervention duration (e.g. ≤ 6 weeks, 7 to 12 weeks, 13 to 23 weeks, ≥ 24 weeks). Where studies are considered similar enough in terms of populations, intervention, outcome measures and timing of outcome assessment to allow pooling of data using meta-analysis, we will assess the degree of heterogeneity by visual inspection of forest plots and by examining the Chi² test for heterogeneity. Heterogeneity will be quantified using the I² statistic. An I² value of 50% or more will be considered to represent substantial levels of heterogeneity, but this value will be interpreted in light of the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi² test (Higgins 2011b). Where there are too few trials included in a meta-analysis, the Chi² test has little power to detect heterogeneity. In such instances a non-significant result will be interpreted with care and will not be taken as evidence of no heterogeneity. Where we detect substantial clinical, methodological or statistical heterogeneity across included studies we will not report pooled results from meta-analysis but will instead use a narrative approach to data synthesis. In this event we will attempt to explore possible clinical or methodological reasons for this variation by grouping studies that are similar in terms of populations, intervention features, and timing of outcome assessment, by sub-group analyses.

Assessment of reporting biases
We will assess reporting bias qualitatively based on the characteristics of the included studies (e.g. if only small studies that indicate positive findings are identified for inclusion), and if information that we obtain from contacting experts and authors of studies suggests that there are relevant unpublished studies. If we identify sufficient studies (at least 10) for inclusion in the review we will construct a funnel plot to investigate small-study effects, which may indicate the presence of publication bias. We will formally test for funnel plot asymmetry, with the choice of test made based on advice in Sterne 2011 and bearing in mind when interpreting the results that there may be several reasons for funnel plot asymmetry.

Data synthesis
We will decide whether to meta-analyse data based on whether the included studies are similar enough in terms of participants, settings, intervention, comparison and outcome measures to ensure meaningful conclusions from a statistically pooled result. Due to the anticipated variability in the caregiver groups, interventions including timing of intervention delivery and outcome measurement instruments used in the included studies, we will use a random-effects model for meta-analysis. Within the data categories we will explore the main comparisons of the review: telephone interventions delivered by healthcare professionals versus usual care and telephone interventions delivered by healthcare professionals versus a support intervention delivered by a healthcare professional that is not telephone based, for persons caring for adults with diagnosed acute or chronic illness. For results that cannot be meta-analysed we will provide a narrative analysis of the data. For results that are narratively synthesised the main results will be grouped according to the categories that best explains the heterogeneity of the studies, which may include intervention type (education or psychosocial), caregiver group, illness type (acute or chronic) and timing of outcome data collection (short-term completion of the intervention to ≤ 3 months; medium-term > 3 to ≤ 6 months; and long-term > 6 to 12 months). Within each category we will present the data in tables and narratively summarise the results.

Subgroup analysis and investigation of heterogeneity
Potential explanatory factors include type of condition (acute or chronic), caregiver group (diagnosis), intervention type (education or psychosocial support) and form of delivery (individual or group). If there are sufficient studies to allow for subgroup analysis we will conduct analysis separately on the primary outcomes for the following groups.

1. Intervention type (education, psychosocial, education and psychosocial combined).
2. Approach to telephone intervention delivery (group, one-to-one).
3. Caregiver characteristics (condition of the person being cared for grouped by category of condition (e.g. cardiac, cancer or respiratory), gender, age (young/older caregivers), relationship to the care recipient).
4. Acute versus chronic illnesses.
5. Intervention duration (≤ 6 weeks, 7 to 12 weeks, 13 to 23 weeks, ≥ 24 weeks).

Sensitivity analysis
We will examine the impact of studies that are categorised as high risk of bias on the outcomes of the overall meta-analysis. Studies identified as having the highest risk of bias will be removed from the analysis. We will also explore the influence of excluding unpublished studies and large studies on the overall effect size. We will also assess the effects of imputed data on pooled effect estimates; for example, removing from the analysis cluster RCTs where ICC values have been obtained from external sources.

'Summary of findings' table
We will prepare a ‘Summary of findings’ table to present the results based on the methods described in chapter 11 of the Cochrane Handbook for Systematic Reviews of Interventions (Schünemann 2011). We will present the results of meta-analysis for the major comparisons of the review, for each of the primary outcomes, and the potential harms/adverse events, as outlined in the ‘Types of outcome measures’ section. Where more than one outcome is reported per category we will use the methods described above to select outcomes for reporting in the ‘Summary of findings’ tables.

We will provide a source and rationale for each assumed risk cited in the table(s), and will use the GRADE system to rank the quality of the evidence using the GRADEprofiler (GRADEpro) software (Schünemann 2011). If meta-analysis is not possible, we will present results in a narrative ‘Summary of findings’ table format, such as that used by Chan 2011.

Ensuring relevance to decisions in health care
The protocol and review will receive feedback from at least one consumer referee in addition to a health professional as part of the Cochrane Consumers and Communication Group’s standard editorial process. During the development of the review, a carer representative group will be asked to provide comment.

Acknowledgements
We thank the editors and staff of the Cochrane Consumers and Communication Group, particularly our managing editor Megan Prictor and co-ordinating editor Sophie Hill and deputy co-ordinating editor Rebecca Ryan, for their input to this protocol. We thank the Health Research Board Ireland for awarding a Cochrane research fellowship to MC for the conduct of this systematic review.

We wish to thank an anonymous caregiver who has commented on the protocol, in particular the outcomes and strategies sections.

References

Additional references

Archbold 1990

Aubin 2012

Badr 2016

Bakas 2009

Bank 2006

Bauer 2009

Bellg 2004

Borman 2009
Telephone interventions, delivered by healthcare professionals, for educating and psychosocially supporting informal caregivers of adults with diagnosed illnesses (Protocol)

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Telephone interventions, delivered by healthcare professionals, for educating and psychosocially supporting informal caregivers of adults with diagnosed illnesses (Protocol)

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Telephone interventions, delivered by healthcare professionals, for educating and psychosocially supporting informal caregivers of adults with diagnosed illnesses (Protocol)

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McCullagh 2005

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O’Shaughnessy 2010

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Piamjariyakul 2013

Pinquart 2003
Plank 2012

Ravenson 2016

Reinhard 2008

RevMan 2014 [Computer program]

Riess-Sherwood 2002

Rivera 2008

Robinson 2005

Roick 2007

Rosland 2008

Rosland 2010

Ryan 2013

Salfi 2005

Santin 2012

Savage 2004

Scherbring 2002

Schünemann 2011

Selwood 2007

Sepulveda 2008

Shozi 2013

Smith 2004

Smith 2006
Sterne 2011

Thompson 2007

Topo 2009

Toseland 1989

Tremont 2008

Unson 2016

Van Mierlo 2012

Vermeulen 2015

Vernooij-Dassen 2011

Vos 2015

Walsh 2003

WHO 2006

Williams 2015

Wilz 2016

Wolff 2006

Zwaanswijk 2013

Zwicker 2010

* Indicates the major publication for the study
Appendix 1. MEDLINE search strategy

1. exp family/
2. (family or families or parent$2 or relative? or spous$2 or partner? or husband? or wife or wives or child or children or grandchild* or son? or daughter? or sibling? or brother? or sister? or mother? or father?).tw.
3. friends/
4. (friend? or significant other?).ti,ab,kw.
5. 2 or 4
6. (care* or caring).ti,ab,kw.
7. 5 and 6
8. caregivers/
9. (care* or caregiv* or care giv*).ti,ab,kw.
10. exp home nursing/
11. or/1,3,7-10
12. exp telephone/
13. (telephon* or phone? or phoning or calls or callback* or call* back* or cellphone? or smartphone? or iphone? or skype).ti,ab,kw.
14. mobile applications/
15. (mobile device* or mobiles or mhealth or m-health or (portable adj2 app*)).ti,ab,kw.
16. exp telemedicine/
17. telenursing/
18. (telemedicine or tele-medicine or telecare or telehealth* or tele-health* or telenursing or ehealth or e-health).ti,ab,kw.
19. hotlines/
20. (hotline* or help line* or helpline*).ti,ab,kw.
21. or/12-20
22. 11 and 21
23. exp health personnel/
24. ((health* or medical or paramedical or nurs* or hospital or operating-room or psychiatric or pharmac*) adj2 (personnel or provider* or professional* or practitioner* or worker* or aide* or assistant* or staff or officer* or specialist* or consultant*)).ti,ab,kw.
25. (doctor* or physician* or general practitioner* or gp or gps or nurse* or clinician* or dentist* or pharmacist* or anesthesiologist* or surgeon* or obstetrician* or gyn*ecologist* or geriatrician* or gerontologist* or therapist* or physiotherapist* or audiologist* or dietitian* or nutritionist* or psychologist* or psychiatrist* or psychotherapist* or counselor* or counsellor* or social worker* or welfare worker*).ti,ab,kw.
26. or/23-25
27. 22 and 26
28. randomized controlled trial.pt.
29. controlled clinical trial.pt.
30. randomized.ab.
31. placebo.ab.
32. drug therapy.fs.
33. randomly.ab.
34. trial.ab.
35. groups.ab.
36. or/28-35
37. 27 and 36
CONTRIBUTIONS OF AUTHORS

Margarita Corry (MC) co-ordinated the protocol, wrote the first draft, contributed to subsequent drafts and prepared the final draft for submission. All other authors - Valerie Smith (VS), Kathleen Neenan (KN) and Sally Brabyn (SB) - contributed to the drafting of the protocol and reviewed it for intellectual content. Margarita Corry is the review’s guarantor.

For the review MC will co-ordinate, lead on each step of the process and write the first draft.

VS will provide overall guidance to MC throughout the review and will act as adjudicator on aspects of the study where there is disagreement amongst the other authors. She will independently check the outcome data entered into RevMan against the data extraction sheets and contribute to the analysis of the data and write-up of the review.

KN will assist with study selection, data extraction and drafting of the review.

SB will assist with study selection, data extraction and drafting of the review.

DECLARATIONS OF INTEREST

- Margarita Corry: I have completed a pilot feasibility study of a telephone support intervention for caregivers of people with multiple sclerosis using the RCT design. I will not be involved in assessing the study for inclusion, extracting or analysing data from that study.
  - Valerie Smith: none known
  - Kathleen Neenan: none known
  - Sally Brabyn: none known

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- Health Research Board, Ireland.
  Awarded a Cochrane fellowship to MC for the conduct of this systematic review

NOTES

This protocol is based on standard text and guidance provided by Cochrane Consumers and Communication (CCCRG 2016).