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Research Protocol

Enhancing existing formal home care to improve and maintain functional status in older adults: Protocol for a feasibility study on the implementation of the Care to Move (CTM) programme in an Irish healthcare setting

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Abstract

An increasing ageing population leads to greater demand for care services to help maintain people in their own homes. Physical activity programmes have been shown to improve older adults' functional capacity, enabling the older adult to live independently and maintain functional status. There has been a lack of quality research conducted around physical activity within the landscape of home care services. We describe a feasibility study of implementing the Care to Move (CTM) programme in older adults receiving low-level home care. A Phase 1 mixed-methods feasibility study design will explore the recruitment, attrition, retention, costs to deliver and data loss. It will also explore the acceptability and impact of the CTM programme on older adults and thematic analysis of data collected from older people, home care workers and relevant stakeholders through use of semi-structured interviews and focus groups. We will measure functional status and fall outcomes in older adults receiving low levels of home care, facilitating this population to continue living independently at home and providing data currently not known around this group.

Keywords: Community-dwelling, Feasibility, Home care, Older person, Physical activity-based

Introduction

Ireland, like many other countries, has seen a steady increase in life expectancy and has an ageing population. Projections indicate that by 2021 the number of older people will have grown by 200,000 and the numbers over 65 will reach 1.4 m by 2046¹. Specifically, the Economic and Social Research Institute (ESRI) project a 94.0% increase in the number of people aged 80 years and older nationally between 2015-2030². This marked increase will be relevant in areas such as Dublin North City where the population aged 80 years and over currently remains higher than the national average at 3.2%³.

Bex Townley and Dawn A. Skelton are Directors of Later Life Training Ltd, a not for profit company delivering training in exercise delivery with older people, including the Care To Move Approach. The remaining authors declare no conflict of interest.

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While formal home care has been identified as one key strategy to support independent living, the ability of social and health care funding to keep pace with growing demand has come under scrutiny in recent years as those receiving home care services are increasing in numbers and have varying levels of support required^{4,5}. Between 2000 and 2010, there has been a fourfold increase in the number of people in receipt of home care services⁵. Currently, 97% of formal home care is financed by the Irish state⁶. The current service configuration poses challenges in the trajectories of care.

The concept of frailty is increasingly used to describe the situation of a large proportion of older people receiving home care. They are at risk of being unable to recover from adverse events, such as falls and their care needs may escalate over time⁷. Those transitioning into frailty are particularly sedentary and avoid activity often for fear of falling^{8,9}. A recent internal review of around 1,300 Irish low level home care service users showed increasing age and a higher frequency of care hours to be significantly associated with greater levels of frailty and 75% of home care recipients assessed, were categorised as vulnerable, mildly frail or moderately frail indicating the relevance of an intervention aimed at this group³.

There has been strong interest in developing innovative and cost-effective interventions to support older people living in their homes and, in turn, to reduce demand on acute hospital services and residential care provision¹⁰.

There has been extensive research into structured exercise programmes for frailer older people or those with sarcopenia¹¹⁻¹³. However, uptake and adherence to such interventions is often poor¹¹⁻¹³. Home care is also an important arena to address falls prevention and QOL, but this vulnerable group of older adults is underrepresented in health research¹⁴. One recent study of a falls prevention exercise programme based on the Otago Exercise Programme (OEP) significantly improved physical function, Health Related Quality of Life (HRQOL) and balance in older adults receiving home care but was cost intensive¹⁴. Integrating strength and balance activities into daily life activities has shown better adherence but there are less studies in those receiving care¹⁵.

Research around structured exercise programmes has been completed in different groups of community-dwelling older people, however few studies have focused on the older population receiving formal home care. A recent systematic review of physical activity programmes for older people receiving home care identified few consistencies and recommended the need for more evidenced based trials investigating physical activity promotion programmes tailored for this group of older adults^{16,17}.

Research, specifically with home care clients, has shown that older people prefer integrated lifestyle exercise and being physically active through activities they enjoy, rather than more structured exercise programmes¹⁸. Through the Care To Move (CTM) programme participants are encouraged to

do more 'movement' associated with self-care activities and, with support, integrate some strength and balance activities into their day as opposed to a prescribed set of exercises conducted for a set amount of time¹⁹. CTM is a whole workforce approach, because its primary aim is to bring consistency (of language, correct messages) to teams delivering packages of care or those regularly engaging with older people in their homes. CTM provides a series of consistent 'movement prompts' to use and embed into existing movements of daily living and offers a series of key messages to communicate during all interactions about sitting and moving more with a view to encouraging and empowering older people to make different decisions in the longer term to better contribute to their health, well-being, confidence and independence. The purpose of intervening in the group is to delay functional decline, thereby maintaining independence and reducing the need for increased formal home care. Although there have been promising local service evaluations of CTM, there has been no formal research published.

The aim of this study is to investigate the feasibility and acceptability of implementing the CTM programme in older adults living in the community who are receiving low-level home care. Through enhancing home care services, this research will aim to evaluate a more sustainable approach to ageing in place as supported by current strategies for health and well-being in Ireland. By incorporating older adults receiving low-level home care this study is attempting to reduce rates of functional decline in this vulnerable older group. If functional status can be maintained or improved it may delay or prevent increased use of formal home care.

Materials and methods

Study design

Phase 1 Feasibility study exploring the potential for a future randomised controlled trial (RCT) of the Care to Move (CTM) programme in the context of a community physiotherapy service with older service users receiving low-level home care support. We will apply Bowen's framework for feasibility studies²⁰ the recent guidelines for reporting non randomised feasibility studies²¹ and will follow the Medical Research Council (MRC) framework for complex interventions²².

Participants and recruitment

Recipients of low-level home care will be recruited from a not-for-profit home care company located in Dublin North City. Care managers, supervisory staff and home care workers will review and screen a list of all service users based on inclusion and exclusion criteria. **Inclusion Criteria:** Service users will be eligible to participate if they are aged 65 years or older, have a Clinical Frailty Score⁷ of 6 or less, have fallen at least once in the last year, receive ≤5 hours of home care a week and are independently mobile (with or without a walking aid). **Exclusion Criteria:** Service users will be excluded

if they have moderate to severe cognitive impairment, have any unstable clinical conditions, are receiving end of life care, or would be unable to follow instructions about exercising, moving or being more physically active, safely.

Procedure

Eligible service users will be provided with a study invitation letter and participant information sheet and will receive a follow-up call within a week to establish if they would like to participate. Following identification of suitable participants, a face-to-face meeting will be arranged with the research physiotherapist to discuss the project. Participants will be given up to seven days between receipt of the study information and being requested to give written permission. Withdrawal from the study will not impact on the level of home care received. Subsequent home visits will be arranged and completed by a research physiotherapist to obtain written consent and to provide any further information regarding the study. Participants will then receive the CTM intervention for six months. Assessments will be completed during home visits at baseline, after 8 weeks of the intervention and at 6 months by a research physiotherapist.

Description of Care To Move (CTM) intervention

We will report the CTM intervention according to the TiDiER Guidelines²³. CTM provides a series of consistent 'movement prompts' to use and embed into existing movements of daily living and offers a series of key messages for care staff to communicate during all interactions about sitting and moving more with a view to encouraging and empowering older people to make different decisions in the longer term to better contribute to their health, well-being, confidence and independence. CTM is not a structured exercise programme but is specifically designed to give home care workers and volunteers confidence to have empowering and motivating interactions with clients, patients and service users across any setting or service working with older people. CTM training was originally designed for a domiciliary enablement service in South Wales and following extensive observation of care visits and discussion with care service leads and therapy leads the training outcomes were designed in recognition of the missed opportunities observed, and to address a clear unmet training need for non-qualified workforce (who have the most opportunities for interaction with service users/patients/older people).

In this study the identified staff (home care workers) trained in CTM (CTM Motivators) will complete a two day CTM course. The CTM course has three key themes/approaches; Communication skills to have purposeful conversations about movement (providing a structured framework); A series of targeted, specific movements and prompts (for key movements already being performed as part of the usual package of care, daily living); Where applicable, motivating and empowering older people to carry out home exercise programmes prescribed by therapy services. Key members

of the team will also be trained as CTM Key Trainers (cascade training for future CTM Motivators) for sustainability. The CTM participants will be encouraged to undertake movements specifically prescribed to improve balance or increase strength. These activities will be embedded within everyday activities; so that the movements can be done several times during the day rather than a prescribed set of exercises conducted for a set amount of time. The duration of the CTM intervention will be eight weeks. During the initial eight weeks, the research physiotherapist will work with the home care worker (i.e. CTM Motivator) and the participant (i.e. home care client) to demonstrate how the movements can be completed safely and effectively over 3 visits. A fourth follow-up visit will then be completed by the research physiotherapist after 6 months to complete the final assessment. Over the study period, it will be the role of the home care worker to encourage and prompt the participant to engage in the CTM programme on their home care visits, which will occur at least once a week. The TiDiER²³ standardised reporting guidelines for intervention description and replication will be followed to ensure the standardised conduct and reporting of the CTM programme (Appendix 1).

Health behaviour change

During the delivery of training in CTM to the home care staff and key trainers, the CTM intervention was mapped against Behaviour Change Techniques (BCTs) from the COM-B Taxonomy²⁴. We will conduct interviews with the study participants, and home care workers. The interviews will be grounded in social-cognitive theory²⁵, exploring the theoretical proximal determinants of behaviour (e.g. self-efficacy, outcome expectancies, self-regulation). This theory will also be used in the actual intervention, which will allow for appropriate process evaluation²⁶ to produce a logic model for implementation that can be tested in a later study. Home care workers will be key to delivering CTM, by motivating and encouraging participants beyond the collaboration with the physiotherapist. We will look at the home care organisation documents, to identify if participants' goals change over time (i.e. did they show progression?) so as to document the participant adherence to the movements recommended over time.

Outcome measures

Primary outcomes: Our primary outcomes will be based on the feasibility of the CTM intervention and data collection across the study period. These will include: number of home care clients that are recruited (recruitment), that provide data at 8 weeks and 6 month follow-up (retention), and show engagement with CTM and progression over time using care documentation (adherence). The primary outcome of the future definitive RCT will be decided by the responsiveness to change, participant burden and participant feedback from this study. We will document data loss in the questionnaires and tests within the secondary outcome measures and document any adverse events related to the CTM intervention.

Secondary Outcomes: All participants will be assessed at baseline, after 8 weeks and 6 months. The main secondary outcome will be Timed Up and Go (TUG) test²⁷. We have a series of validated questionnaires to assess: Frailty⁷ (Rockwood); level of physical activity - PhoneFITT²⁸; Nottingham Extended Activities of Daily Living (NEADL) scale²⁹; Lower body strength, as measured by performance of 30-second chair stand test³⁰. Balance confidence will be assessed with the shortened 10-item Activity specific Balance Confidence (ABC) scale³¹, and the CONFBal – a 10-item falls self-efficacy scale³². Quality of life will be assessed using the SF-36 and EuroQOL EQ5D-5L questionnaires³³. For social cognitive theory (SCT), a validated SCT scale will be used³⁴. We will produce a logic model for implementation that can be tested in a future study. We will explore the capacity to deliver the intervention in the context of community physiotherapy services working in partnership with a home care organisation, examine delivery (fidelity) and compliance of the intervention. Participants will be asked to complete a weekly report to be collected by the home care worker in which they will monitor any falls or major health changes and health care use. Participants will be given a weekly calendar to tick each day they performed an activity during the study period.

Health economic evaluation

We will examine the implementation and running cost of the CTM-programme, assess the health economics outcomes in terms of improved functional ability and health-related quality of life (including quality-adjusted life years), and down-stream use and cost of health and social care resources. A model-based cost-effectiveness analysis will be calibrated with best available data (including data from the prospective data collection) and applied to assess the cost-effectiveness of scenarios with CTM implemented at different scales and in different settings. The model will further be explored in a Value-of-Information analysis to describe the potential benefit from future research and in particular provide information about the optimal sample size of future clinical trials of CTM interventions³⁵.

Sample size

This study is a feasibility study and so no formal power calculation has been carried out. Part of this feasibility study will assess whether enough participants can be recruited and retained in the study and outcome data generated to inform the potential for a future Phase II study. We have therefore not powered the study for specific outcomes but aim to recruit 40 participants with the goal of retaining 30 to follow-up. The sample size was deemed to give sufficient insights into the intervention implementation and data collection process, and sufficient data to conduct meaningful analysis and to be relevant for sample size calculation for a future randomised study. The attrition rate varies between 15% and 30% as demonstrated by previous physical activity studies³⁶⁻³⁸.

Data analysis

Baseline demographic and outcome variables will be described at all assessment times. Information on missing or incomplete data from all outcome measures will be reviewed. Although not powered for effectiveness, tests will be completed with a 0.05 level of significance. To consider trends in outcome measures, the change in scores from baseline to T2 to T3 in the various outcome measures will be calculated. The data will be inputted into Stata version 16 (Texas, USA). Descriptive statistics will be primarily used. We will conduct focus groups and interviews to ascertain the views and experiences of participants and home care staff. Open-ended responses from the qualitative interviews and focus groups will be analysed thematically using an approach described by Miles and Huberman³⁹. The health economic costs of the programme as well as the costs of other health and social care will be described. A decision analytic model will be developed using data from the performed data collection and supplemented with data from other sources. Different scenarios for service organisation and the effectiveness will be described using this model and their relative cost-effectiveness in comparison with no CTM program will be calculated. Sensitivity analysis will show the cost-savings and improved effectiveness that should be achieved in order for that intervention to be cost-effective and what additional data collection or quality control will be needed in a Phase II study.

Ethical considerations

Ethical approval has been granted by the Royal College of Surgeons in Ireland Research Ethics Committee (REC -2018:1489).

Acknowledgments

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Disclaimer

Prof. Dawn Skelton serves as Co- Editor in Chief in the JFSF. The manuscript underwent peer review process by independent experts.

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Appendix 1. TIDieR (Template for Intervention Description and Replication) Checklist*:

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Care To Move (CTM).	__10 & 12__	https://www.laterlifetraining.co.uk/courses/care-move-ctm-course/
	WHY		
2.	CTM provides a series of consistent 'movement prompts' to use and embed into existing movements of daily living. The aim is for home care recipients to move more and sit less.	__12__	https://www.laterlifetraining.co.uk/courses/care-move-ctm-course/
	WHAT		
3.	Materials: CTM diary provided to participants by home support workers. The diary includes an information sheet, CTM plan and CTM client record.. CTM Client Record for completion by the care staff which includes which ADL tasks client has agreed to movement prompts and recommendations for continuation of practice of movements.	__12__	https://www.laterlifetraining.co.uk/courses/care-move-ctm-course/
4.	Procedures: On Client Record: At start of visit (tick-box): <ul style="list-style-type: none"> • Your greeting had a 'movement' check • Discussed 'how' they moved since last visit • Discussed any previous successes • Started planning for today's tasks with a key focus & messages (Set up the task and review on completion of every task – proactively encouraging feedback/staying engaged with the task) During ADL Tasks (tick-box): <ul style="list-style-type: none"> • Used 'Prepare to move' prompts regularly • Used prompts to improve active posture In sitting • Used prompts to help with bum shuffle • Used prompts to help mobility /circulation • Used prompts to help stand up or sit down • Encouraged them to 'power up' through heels and legs • Reminded to pause on stand • Reminded to foot pedal before walking • No talking when walking or changing direction • Used prompts to help ADL's in standing: heel raises/ knee bends Before Leaving (tick-box): <ul style="list-style-type: none"> • Reviewed any movement successes • Discussed movement plan for next visit and left a 'seed of thought' Recommended they continue practicing prompts during tasks: <ul style="list-style-type: none"> • In bed • In sitting • When dressing/ washing • When standing up • When toileting • When walking/ turning • Other: 	__12__	https://www.laterlifetraining.co.uk/courses/care-move-ctm-course/

	<p>General reminders:</p> <ol style="list-style-type: none"> 1. Movement Conversations with clients 2. Movement Prompts and understanding of purpose/benefits 3. Movement Empowerment for on-going regular movement <p>"Putting movement on the map"</p> <ul style="list-style-type: none"> • Get your body ready to move ② easier to get out of a chair or bed. • Prepare your joints to move more freely ② so easier to reach, turn and bend to do activities like putting on shoes. • Get your muscles stronger and feel more stable and can do activities easier and for longer. • Get yourself steadier on your feet ② easier to walk and move around for activities at sink, preparing meals etc. <p>Remember no one message suits everyone so you will need a range of prompts and instructions on how to make movement easier or safer for different people. Keep reinforcing the benefits of the movement in relation to their goal of improving something.</p>		
	WHO PROVIDED		
5.	In this study identified homecare staff trained in CTM become CTM Motivators after completing a two day CTM course.	__12__	https://www.laterlifetraining.co.uk/courses/care-move-ctm-course/
	HOW		
6.	During the initial eight weeks, the research physiotherapist will work with the home care worker (i.e. CTM Motivator) and the participant (i.e. home care client) to demonstrate how the movements can be completed safely and effectively over 1-3 visits. A fourth follow-up visit will then be completed by the research physiotherapist after 6 months to complete the final assessment.	__12 & 13__	_____
	WHERE		
7.	CTM will be delivered in the older person's home.	__12__	_____
	WHEN and HOW MUCH		
8.	The duration of the CTM intervention will be eight weeks. During the initial eight weeks, the research physiotherapist will work with the home care worker (i.e. CTM Motivator) and the participant (i.e. home care client) to demonstrate how the movements can be completed safely and effectively over 3 visits. A fourth follow-up visit will then be completed by the research physiotherapist after 6 months to complete the final assessment.	__12-13__	_____
	TAILORING		
9.	Over the study period, it will be the role of the home care worker to encourage and prompt the participant to engage in the CTM programme on their home care visits, which will occur at least once a week. If a client has difficulties or cannot move safely in the particular movement then this movement will be removed from the potential list of movements.	__12__	_____
	MODIFICATIONS		
10.†	As this is a feasibility study we will note any modifications to the intervention as the study progresses.	__12 & 13__	_____
	HOW WELL		
11.	Planned: As this is a feasibility study we will assess intervention adherence or fidelity, this will be conducted by the research physiotherapist.	__12__	_____
12.‡	Actual: N/A at this stage of protocol.		_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use "?" if information about the element is not reported/not sufficiently reported. † If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL). ‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.