Implementation should now be considered in parallel with designing clinical research

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There is little argument that health and social services should be based on or informed by robust evidence and that clinically and cost-effective interventions which are acceptable to people should be incorporated into services. However there is frequently a prolonged time period between research studies being completed and published and their results being implemented. Even when implementation has begun it is often incomplete or unsuccessful. There is added complexity with the implementation of multicomponent non-pharmacological interventions where there are often many permutations of an intervention, which may be individualised for delivery and where the context can vary across real world settings particularly in low and middle income countries with very limited resources.[1] Considerations about time to and difficulties in implementation, has led to the development of implementation theories, which are a practical guide about how to transform research into practice, considering what allows or impedes successful implementation and providing frameworks for how to judge what is successful implementation. [2] Such theories usually consider what is important, possible, practical and evidence informed, incorporate wider stakeholders in an iterative process and try to overcome hurdles which would prevent implementation in practice. [3]

The process of testing an intervention and then implementing it is very time consuming and realisation of these timelines and the disadvantage to patients and families of implementation starting after and separately from research, has led to a change for some funders and academics in the way research is done. Previously researchers would consider what research is needed and then apply for money, gain ethical and other permissions, if necessary design the intervention, gather data, complete, write up and publish the study. While publication is a form of dissemination, implementation was not usually considered as their job. Successful research, in which an intervention worked, was followed by policy makers (sometimes) starting implementation.

Now, many researchers and grant bodies have moved to working in parallel, so that clinical researchers often involve stakeholders, including patients and the public, as well as those working in policy and clinically throughout each stage of the research process. This is particularly illustrated at present by searches for vaccine for COVID-19 which are accompanied by plans to scale up the production and delivery of any vaccine found; while still having knowledge that a vaccine may not be found.[4]

The study published here, Costing resource use of the Namaste Care Intervention UK: a novel framework for costing dementia care interventions in care homes, by Bray et al, [5] takes the approach of cost modelling in parallel with research to consider efficacy and is a step forward in ensuring readiness to integrate research findings into complex and diverse settings. Some of the considerations around implementing an intervention, are the benefits of the intervention and the risks, the costs of it, the cost-effectiveness (so it can be compared to other possible interventions either in the particular field or in other illnesses) and the acceptability in different contexts. This paper is part of wider implementation

study and should be seen as such, where the implementation model runs at the same time as considering efficacy. [5]

Namaste, the intervention which is costed in the accompanying article, refers to an intervention delivered by trained care workers for two hours every morning and evening, to people with advanced or end-of –life dementia in care homes.[6] The multi-sensory intervention includes touch, music, nature, aromas and objects, delivered to people living with advanced dementia or people at end of life with dementia and the benefits are in quality of life or enjoyment. While the whole intervention awaits evidence, its various components seems to improve enjoyment.[6] The intervention incorporates these interventions into a coherent manualised package which itself may increase the likelihood of future implementation at scale.[7] An online survey with practitioners concluded that Namaste has the potential to improve quality of life. [8]

People with more severe dementia and complex needs at the end of life in care homes are often only offered medical and nursing care and attendance to their basic needs, such as washing, medication, eating and pain control, with staff unclear how they can look after other palliative needs.[9-11] Instead they are often excluded from group activities in care home as they are too unwell to attend and participate in them. Agitation is common and staff may consider it as purposeful and avoid the person with dementia or as indicating distress and try to help but it is often difficult for them to know what to do.[11] Staff may feel that if residents are admitted to hospital will have better care, although the residents and families would judge that they may do better with familiar staff and surroundings. [12]

Being able to establish the realistic costs of delivering and intervention is important because it allows policy makers or care home owners and managers to budget and implement effectively. Researchers are often asked to give details on what costs will look like beyond that which has been established during a tightly controlled research study, where costings and the resources required may change outside of the research setting. Here the authors lay out the need to consider practice based evidence and to adaptively allow the development of different models of delivery. This is consistent with the 'dynamic sustainability framework' of implementation which argues for the ongoing learning and adaptation of interventions to fit local organizational and cultural contexts[1]. The model presented here for Namaste care lays out clearly a methodology to consider costs which may be applicable in other contexts, in a step towards offering care home decision makers and commissioners a basis for deciding whether and how to implement it.

The authors have been thorough in creating the cost model and considering real life implementation of Namaste for such residents. This method shows that what may initially be assumed to be a very expensive intervention, with four hours of one to one care a day, costs relatively little. Surprisingly, the model does not include costing for training staff and presumably the need to replace them with other staff during the training. This set up cost is important although not part of ongoing costs. They have tried to account for context and complexity and have modelled three levels of provision. The model can be used to calculate the cost per resident per session which is very clear and helpful for decision makers.

The cost model here is UK specific as costing of an intervention has to always begin in a specific geographical area and health and social care system, with explicit methods which allow those who would use it in other care systems to consider how it would apply in a different country. The model is dynamic, easy to use and adjustable. They plan to integrate and test their model with real life data from an implementation study which means that they can adapt the model and present different options for

implementation. The cost model is useful for care home providers who are looking to implement new ways of working, to help them to consider in their own specific context what would be feasible and also what impact delivering the intervention may have on staffing and the details of what is involved in practice in these sorts of interventions.

We await to hear further about the efficacy and practicality of implementation Namaste and the model chosen. This involves many factors. These include whether it is it acceptable to staff implementing it and those who are expected to benefit, bearing in mind they may be a more diverse group than that in which it was designed. Feasibility also includes whether staff time can be made available to implement it, designing training packages for staff and ensuring fidelity in delivering the intervention. The other costs are opportunity costs (what else will you not implement) and risks of the intervention, as well as financial costs. This original and clear model of costs of implantation can help others, in the future, build a platform for implementation using the same process, in tandem with considering other evidence required.

1. Chambers DA, Glasgow RE, Stange KC. The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. Implementation Science 2013;8:117.
2. Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci 2015;10:53.
3. Kwok EYL, Moodie STF, Cunningham BJ, Oram Cardy JE. Selecting and tailoring implementation interventions: a concept mapping approach. BMC Health Serv Res 2020;20:385.
4. Framework for decision-making: implementation of mass vaccination campaigns in the context of COVID-19: WHO, 2020.
5. Bray J, Brooker D, Latham I, Wray F, Baines D. Costing resource use of the Namaste Care Intervention UK: a novel framework for costing dementia care interventions in care homes. Int Psychogeriatr 2019:1-10.
6. Bray J, Brooker DJ, Garabedian C. What is the evidence for the activities of Namaste Care? A rapid assessment review. Dementia (London) 2019:1471301219878299.
7. Froggatt K, Patel S, Perez Algorta G, et al. Namaste Care in nursing care homes for people with advanced dementia: protocol for a feasibility randomised controlled trial. BMJ Open 2018;8:e026531.
8. Bray J, Atkinson T, Latham I, Brooker D. Practice of Namaste Care for people living with dementia in the UK. Nurs Older People 2019;31:22-28.
9. Livingston G, Pitfield C, Morris J, Manela M, Lewis-Holmes E, Jacobs H. Care at the end of life for people with dementia living in a care home: a qualitative study of staff experience and attitudes. International Journal of Geriatric Psychiatry 2012;27:643-650.
10. Sampson EL, Burns A, Richards M. Improving end-of-life care for people with dementia. Br J Psychiatry 2011;199:357-359.
11. Sampson EL, Stringer A, La Frenais F, et al. Agitation near the end of life with dementia: An ethnographic study of care. PLoS One 2019;14:e0224043.
12. Livingston G, Sommerlad A, Orgeta V, et al. Dementia prevention, intervention, and care. Lancet 2017;390:2673-2734.