



Research made simple: developing complex interventions

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In common with many other countries, population ageing, advancements in medical technology, changing disease profiles, the influence of lifestyle choices on health and increased patient expectations are driving health and social care provision in the UK. As the number of people living with one or more long-term conditions rises, interventions to support their health and well-being become increasingly complex. Nurses will not only be expected to deliver complex interventions but are in an ideal position to contribute to priority setting and the development and evaluation of interventions that meet patient needs. It is essential that complex interventions are based on the best available evidence and evaluated if they are to improve health outcomes. In this article we will provide an overview

of complex interventions, using dignity therapy as an example, and outline the principles of developing a complex intervention.

What is a complex intervention?

The UK Medical Research Council (MRC) defines complex interventions as those with several interacting components.¹ In addition, interventions can be thought of as complex if they are dependent on the behaviours of those delivering and receiving the intervention, there are a range of possible outcomes, or there is a need to tailor the intervention to different contexts and settings.¹

In palliative and end of life care (EoLC) settings, helping people make sense of their lives is as important as managing disease symptoms. Dignity therapy (DT) is

Table 1 Framework for developing a complex intervention⁸ applied to EoLC interventions and MORECare guidelines¹¹

| Activities | Considerations |
|-------------------------------------|--|
| Planning | Identify the problem, and why a change is required, its importance and what would be the benefits of a new intervention. Identify current interventions—what does and does not work. Identify resources required both in terms of time (be realistic) and funding Understand the context (population and individuals; location or geographical setting; social, economic, cultural and political influences) where the intervention will be implemented. Understand the facilitators and barriers to reaching the relevant population |
| Involve stakeholders | Identify and involve all stakeholders (commissioners of services, health professionals who deliver interventions, and patients and carers who will benefit from the intervention) throughout the development process ► It may be appropriate to adjust eligibility criteria for participants in EoLC in order to recruit patients who may benefit the most from the intervention |
| The team | It is essential the development team includes individuals with relevant expertise in relation to the problem being addressed, including stakeholders, and the methodological experts to support the collection of evidence ► Researchers need to be familiar with the challenges in EoLC studies. Ideally involvement with stakeholders would be established prior to the study and continue beyond individual studies. It is also important to minimise the burden for clinical staff who participate |
| Establish the evidence-base | Review and synthesis published research evidence before starting to develop the intervention to understand the evidence base for each component of the intervention |
| Draw on theory | Identify existing theory/ theories or frameworks that will inform the development of the intervention, eg, psychological and organisational theories |
| Develop and design the intervention | Collect qualitative data to generate ideas about the content, format and delivery of the intervention. Identify outcomes and what measures exist to evaluate outcomes using quantitative methods EoLC measures should be chosen that meet the following criteria: ► Established validity and reliability in a relevant population ► Responsive to change over time ► Capture clinically important data ► Easy to administer and interpret (concise and not complex) ► Applicable across care settings to capture a change in outcomes by location (eg, home, hospice and hospital) ► Able to be integrated into clinical care ► Minimise problems of response shift (a change in conceptualisation or calibration of what is being measured) ► In addition, and central to complex interventions is the experience of 'care'- allowing enough time for the intervention to have had an effect is important. The plan of investigation and methods should not cause unnecessary burden on participants. The therapeutic effect of interviewing, if a component of the intervention should also be considered during evaluation |
| Testing the intervention | Write up the intervention development process so that judgments can be made about the quality of the process. Develop a protocol for the feasibility/pilot or evaluation of the intervention ► Consider issues of attrition when developing protocols in EoLC, because attrition rates can influence decisions during the implementation of interventions. Estimate in advance possible reasons for attrition and missing data when calculating sample sizes and allow for data collection phases from proxies. Use the MORECare classification to describe the causes of attrition: ► Attrition due to death ► Attrition due to illness ► Attrition at random ► Consider implementation implications, eg, workforce and training needs at all stages of intervention development, testing and integration into practice. ► Data on the use of services needs to be collected to explore impacts on care costs ► Cost-effectiveness outcome measures need to be justified |

EoLC, End of Life Care; MORECare, Methods Of Researching End of life Care.

| Table 2 DCMC and DT ^{12 13} | | |
|--------------------------------------|---|--|
| Theme/Component of DCMC | Meaning | Relevance to DT |
| Generativity | The concept of dignity is intertwined with an internal need for life to have been purposeful and offer some meaning for others beyond their death | The DT interview process is audio-recorded transcribed and edited with the patient to develop a legacy or 'generativity document'. This document is returned to the patient to later share with loved one(s) of their choosing |
| Continuity of self | Being able to maintain a sense of self alongside advancing illness symptoms and physical impacts | Patients are invited to talk about the issues that are important to them, their personhood, sense of self and perceived identity |
| Role preservation | Being able to maintain an association with one or more previously held roles | Patients are invited to talk about previous or current roles that integral to their perceived identity |
| Maintenance of pride | An ability to maintain positive self-regard | Patients are invited to talk about achievements or key memories that have enabled them to experience a sense of pride |
| Hopefulness | An ability to see, achieve and maintain a sense of meaning or purpose | Patients are invited to engage in a therapeutic process that will help them to achieve a sense of their meaning and purpose |
| Aftermath concerns | Worries or fears about the burden or challenges their death will cause others | Patients are invited to talk about issues that might prepare, support and comfort their loved ones in facing a future without them |
| Care tenor | The attitude and manner of others when interacting with the patient to promote dignity | The tenor of dignity therapy aims to be empathic, non-judgmental, encouraging and respectful |

DCMC, Dignity Conserving Model of Care; DT, dignity therapy.

a validated psychotherapeutic intervention designed to bring about a sense of meaning and purpose for individuals at the end of life.² DT addresses psychosocial and existential distress by encouraging patients through focused interviews to discuss valued memories, accomplishments, roles, life lessons and hopes for significant others. Interviews are recorded, transcribed, edited and transcripts returned to the patient, who can add to the document. The format of the documents, typically labelled a 'generativity document' or 'written legacy', is evolving, for example, picture books, including cherished photos alongside briefer key commentaries. Many patients share these documents with significant others, providing opportunity for meaningful conversations that can assist with the bereavement processes. DT can be thought of as a complex intervention because: (1) DT is dependent on the skills of professionals delivering the intervention and the receptiveness of those receiving the intervention; (2) there are a range of outcomes measures that can evaluate the effectiveness of DT such as the Dignity Impact scale³ (a new measure specifically developed as an outcome measure for DT, measuring influences on the spiritual domain of well-being including meaning making, preparation for death and life completion tasks), The Palliative Performance Scale⁴ (assesses psychological, existential and spiritual distress), anxiety/depression scales⁵ and the patient dignity inventory⁶ (a measure of dignity-related distress); (3) DT needs to be tailored to different service settings and patient illness trajectories.

What are the key stages in developing a complex intervention?

Although MRC guidance on complex intervention¹ has been in existence since 2000, methodological development is continuing to progress at a rapid pace. Although multicomponent interventions will be necessary to support patients and their families in an increasingly complex healthcare environment, the reporting of complex interventions has been criticised for not always including all 'ingredients' of the intervention.⁷ For intervention development to be successful, rigorous, structured and methodologically appropriate processes must

be followed.⁸ Involvement of stakeholders throughout the development process is central to producing an intervention that is fit for purpose that meets both health professional and patient needs, and ensures implementation is well-adopted.⁹ Furthermore, the MRC guidelines on complex intervention development emphasise that interventions must be theory-driven in order to understand how they work and in order to achieve the best outcomes.¹ A poorly conceptualised phenomenon results in interventions that are rarely well developed.¹⁰

The Methods Of Researching End of life Care (MORECare)¹¹ statement builds on the MRC guidance in relation to best practice and solutions to developing and evaluating complex interventions within EoLC. It is important to combine MRC guidance with guidance that supports best practice in terms of research design/population needs.¹¹ Table 1 provides a brief summary of the stages that guide the development of complex interventions based on a widely adopted framework developed by O'Cathain and colleagues, combined with components of the MORECare statement that are particularly pertinent to EoLC interventions, such as DT.^{8 11} In addition to effective planning and meaningful stakeholder engagement, the development of a complex intervention includes synthesising the evidence, understanding how the intervention would change behaviours by drawing on existing theory, and patient-focused research to identify its components.

In relation to DT, the intervention evolved from the Dignity Conserving Model of Care (DCMC).¹² The DCMC, the theoretical/conceptual framework underpinning DT was developed from detailed qualitative work. Participants comprised a range of stakeholders including patients and their families, who were invited to explore what constitutes dignity and how it can be achieved or maintained through experiences, cares and interactions. The model contains several themes and related subthemes that informed the schedule of questions and tenor of DT.² Table 2 provides a brief summary of each theme/component of the DCMC^{12 13} and highlights how each theme has influenced DT. Following its initial development, the effectiveness

of DT has been studied in feasibility and randomised control trial studies to evaluate its value for different patient populations and their families.¹⁴ To date, DT is proving to be a supportive psychotherapeutic intervention for middle-aged and older adults.¹⁴ However, further studies are required to develop DT as a complex intervention to support the needs of younger life-limited populations.^{15 16}

In summary, we offer some key considerations to successful complex intervention development in healthcare, with additional considerations for EoLC studies, highlighting through the example of DT as a complex intervention. Research evidence, using mixed methods approaches and theory, inform the content, structure and delivery of complex interventions to increase the likelihood of them being effective. Collaboration with stakeholders through all stages of development, testing and implementation can enhance the perceived value, efficacy and effectiveness of complex interventions.

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