FULL/LONG TITLE OF THE TRIAL: To Co-develop and test an eHealth Intervention tO improve knowledge, attItude and experienCE in patients living with an Implantable Cardioverter Defibrillator

SHORT TRIAL TITLE / ACRONYM: CHOICE-ICD

RESEARCH REFERENCE NUMBERS:

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SPONSOR: Queen's University Belfast

For and on behalf of the Trial Sponsor:

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Signature: Date:

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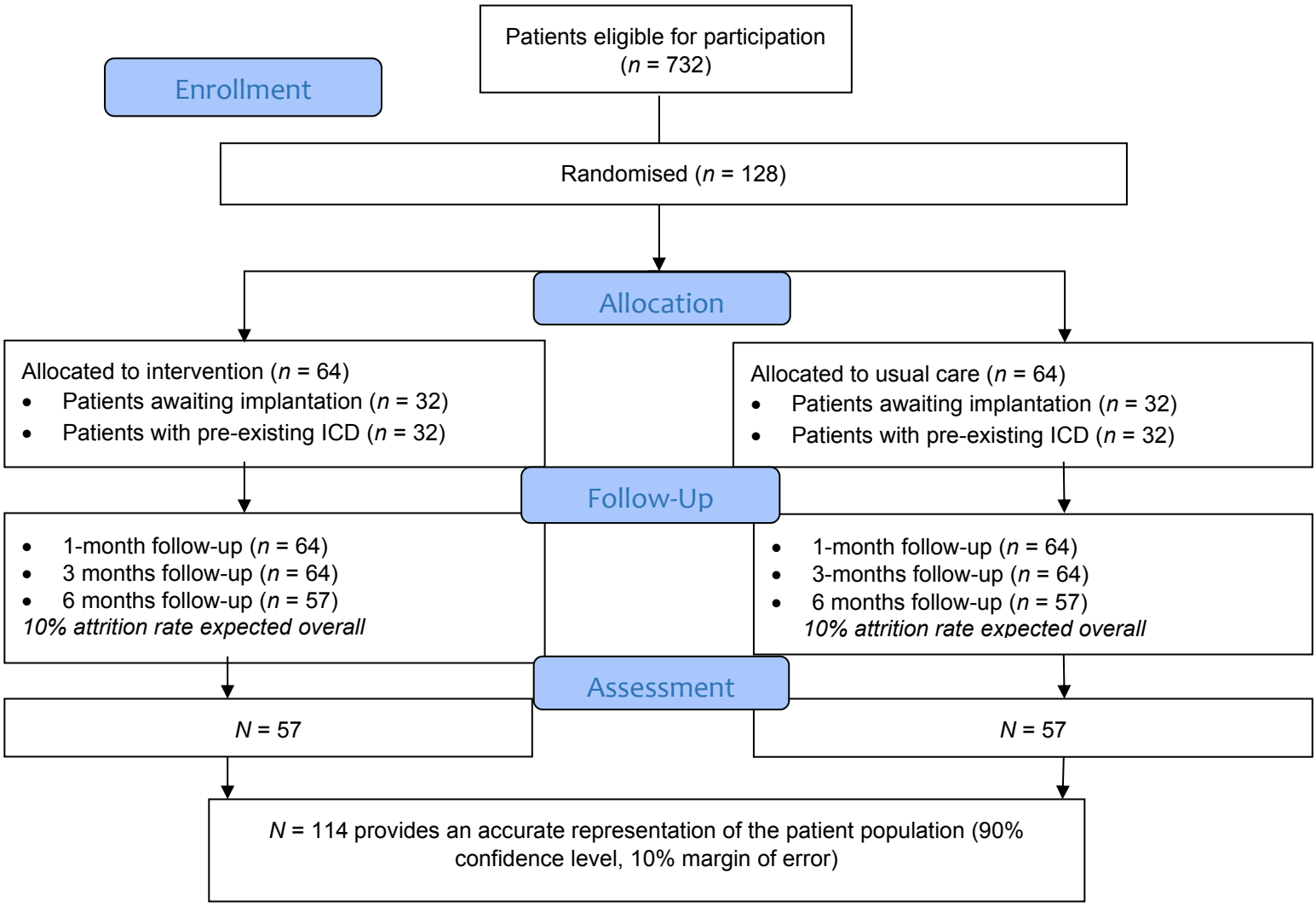
LIST of CONTENTS

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
British Heart Foundation	£315,794.50 over 36 months

Trial Flow Chart (Figure 1)



1: **Abstract**

Implantable cardioverter defibrillator (ICD) is cornerstone in the treatment of life-threatening arrhythmias, yet 25% of patients report poor quality of life following implantation.

Aim: To co-design, optimize and establish feasibility and acceptability of eHealth intervention: CHOICE-ICD website, to reduce anxiety and improve patient involvement in future palliative decisions.

Methods: Phase 1: Underpinned by theory and research, core components of an intervention was co-designed according to a six-step process, in collaboration with stakeholders. Components included ICD written information, educational animations, virtual reality (VR) application, patient and care videos and a communication "prompt" for consultations. An expert advisory group oversaw the iterative development, user testing (n=10) and optimization. Phase 2: CHOICE-ICD is a prospective study, recruiting 128 patients awaiting or recently implanted ICD or cardiac resynchronisation therapy with ICD (CRTd) from Northern Ireland and Glasgow Participants will use the intervention for 3 months. Data will be analyzed to determine feasibility and acceptability.

Outcomes: Recruitment, consent and randomization rates, and completion of questionnaires at baseline,3 and 6 months. Acceptability of intervention delivery and suitability of outcome measures.

Conclusions: First UK eHealth intervention that will provide information to patients with an ICD, tailored to their needs. According to outcomes, plans will be initiated for future effectiveness trial.

2: Background to the project and pilot data

Identification of the problem: Unmet psycho-educational needs

Implantable Cardioverter Defibrillators (ICDs) are recognised as an effective treatment for life-threatening arrhythmias (1), contributing to a worldwide rise in implantation rates. Within the United Kingdom (UK) over 6 thousand ICDs were implanted in 2015 (2), with Northern Ireland (NI) health service implanting a total of 156 devices per million population annually (2016/2017(3)). The combination of Cardiac Resynchronisation Therapy, which is a 3-lead

pacemaker and ICD (CRTd) has transformed heart failure treatment over the last decade, resulting in improved symptoms and quality of life, along with a reduction in hospitalisations and mortality (4, 5). Referral for implantation or battery/generator replacement remains guideline-driven (5, 6), with clinical indicators informing the decision (1, 7, 8). Clinical trials show a short-term improvement in patients' quality of life (9, 10) following ICD implantation, however for some people, the device has a detrimental impact on their psychological well-being and quality of life (11-13), particularly patients who receive frequent ICD shocks. Factors found to contribute to poor outcomes include Type D personality (14), poor illness perceptions (15), unrealistic expectations of treatment and underlying disease progression. Insufficient information can cause patients to misunderstand the functionality of their ICD, overestimating its benefits and prompting maladaptive coping strategies (16). American and Irish studies found 37% to 65% of patients with a recently implanted ICD, were unable to recall or inaccurately recalled the information professionals provided (17, 18). Similar results were noted in NI and Denmark regarding ICD deactivation (19, 20) as nearly half of patients surveyed (48%) reported they received no information. International guidelines state that providing patients with comprehensive information at the implantation stage is critical for ensuring the validity of informed consent (16, 18) as it facilitates an accurate understanding of the device capability and functionality now, and as the clinical condition progresses.

Identifying the evidence: Interventions to inform & support patients with ICD

Effective pre-implantation education has been shown to improve knowledge, psychological acceptance and adaptation to living with the device (11, 21). International guidance recommends patients receive ongoing education and support to facilitate active involvement and improve adherence to measures for long-term health (5, 22, 23). Published guidelines provide healthcare professionals with the necessary knowledge to optimally manage patients with an ICD near the end-of-life (24, 25). Nevertheless, all too often patients reach the palliative stages, unprepared both educationally and psychologically to make informed choices concerning their device. Many professionals working across all clinical settings, in an effort to preserve the patient's hope, are reluctant to initiate a discussion about deactivation(19, 26). Deactivation is a non-invasive process, whereby the shock function of the device is 'turned off',

while remaining functions remain active. At the palliative stage of care patients and family members should be fully informed and involved in decisions concerning future treatment and care provision (27, 28).

In general, patients receive information about their device from professionals, information booklets, device manufacturer brochures or by accessing the internet (29). As a consequence of the Covid pandemic, nearly all adults in the UK now have internet access, with the proportion of those aged over 75 years increasing from 29% (2013) to 54% in 2020 (30). Technological innovation that provides personalised education and support to empower self-management has grown in acceptability with patients (31). Audio-visual aids (32) and an interest in educational virtual reality platforms are wide-reaching, sustainable and cost-effective, and can effectively provide information in a format, and at a time and place convenient to the user. Predictive modelling offered by Artificial Intelligence now makes it possible to personalise educational strategies, in accordance with, for example informational wishes, cognitive ability and clinical status of the patient (33).

A recent systematic review and meta-synthesis, on the perceptions and experiences of patients living with an ICD concluded that interventions should be patient-centric and tailored to patients' holistic needs (34). ACQUIRE-ICD, is an ongoing Danish randomised control trial (35) of a supportive intervention, incorporating cognitive behavioural therapy and psychologist input over a 12-month period. Its primary outcome is device acceptability with secondary outcomes being clinical and cost effectiveness. The CHOICE-ICD study will compliment this study, by co-designing and testing a psycho-educational intervention that integrates practical information, visual aids, patient stories and gamification. In addition to the acceptability and feasibility of the intervention, a composite outcome - knowledge, attitudes and experience, will be measured. This study has developed an intervention to provide tailored information and support, which will require wider testing to enable patients be better equipped and empowered to live well with their device. Therefore, a modern solution for what is increasingly a common clinical problem.

Theory and pilot work: A New approach for ICD patients

Psycho-educational interventions are `complex interventions' consisting of multiple interacting components (36). Exploratory work by this research team has identified the importance of

personalized information and support, beginning at pre-implantation and continuing throughout the illness trajectory (19, 37-39). A stakeholder meeting held in September 2021 with cardiologists, electro-physiologists, nurses, software developers, researchers and patients, confirmed the need for eHealth/website delivery, and discussed potential topics of information. The illness representation or "Common Sense model of Self-Regulation" (CSM) focuses on how an individual's behaviour is influenced by his/her perceptions (40). Perceptions, in the case of the patient with an ICD, may be influenced by the reason for device implantation (41); short and long-term daily adaptations living with the device (42); receiving a shock (18); and the unpredictability of advanced heart failure (43). This model offers a sound theoretical framework to address the psychological and informational needs of patients with an ICD. Using the six-stage 'experience-based co-design' approach, professionals and service users worked in partnership (44-47) to select and optimize the composition of these components. Lessons learned from the development of a supportive intervention within the field of cancer care (48, 49) was implemented. The 'added' value of CHOICE-ICD is that it is a 'state-of-the-art' web-based intervention, made possible by an interdisciplinary team including software developers, patients and family members, with the patient remaining a central partner (50) in decisions. The finalized prototype of the intervention will now be pilot tested by patients within Northern Ireland and Glasgow, optimized based on feedback, before a clinical feasibility trial.

3: **Aim & Objectives**

An eHealth intervention co-designed by patients, family members and professionals will be feasible and acceptable, enabling progression to an effectiveness trial.

Aim of this study

Co-design and test an eHealth intervention for patients' pre-implantation and those recently implanted an ICD, together with family members and professionals.

Objectives of this study

1. To co-develop and pilot test a prototype of an eHealth intervention with patients with an ICD, their family members and professionals.

2. To optimise and deliver the intervention to patients awaiting and those with an implanted ICD, with data collected to determine recruitment/demand, engagement with the intervention (System Usability Scale-SUS) & attrition.
3. To explore the acceptability of the intervention through a questionnaire and focus groups with patients, family members and healthcare professionals.
4. To undertake a process evaluation identifying methodological issues, face and psychometric validity and the primary outcome for a future trial. Self-reported data from validated questionnaires delivered pre- and post-intervention will measure patients' knowledge, attitudes and experiences (EOL-ICD), device acceptance and concerns (ICDc and Florida Patient Acceptance Survey), quality of life (EuroQol-5D), anxiety (BAI) and illness perceptions. Caregivers will complete the carer strain index (CSI)

4: **Trial design:**

This CHOICE-ICD methodology is framed according to the Medical Research Council (MRC) framework (36), and in accordance with the Common Sense model of Self-regulation and previous research conducted by the experienced research team (19, 27, 37, 51-54).

Methods:

This study comprises of two phases, outlined in the Consort diagram (Figure 1) (55) and Gantt chart (Appendix 1) .

Phase 1: Co-design the intervention (Objective 1)

The co-design of the intervention involved a number of iterative steps (48). Previous work conducted by this research team developed the concept of an eHealth intervention. The first integrated workshop stakeholders (n=18; patients with an ICD, family members, cardiologists, heart failure nurses, cardiac physiologists, and software developers) was held on the 8th September 2023. Interaction focused on balancing technical, holistic and practical details, with the provision of clinical facts without evoking fear, in order to create a patient-centred learning environment. Unstructured meetings (online) were held with 10 stakeholders (patient, family members and professionals) who tested and provided feedback on the prototype of the APP, which was conveyed at the forthcoming stakeholder meeting. The prototype was tested at each

iterative stage for two weeks. Within the second stakeholder workshop (n=16), on the 22nd May, feedback from testers (n=8) informed the components of the APP, including content, patient videos, VR option, ease of use and navigation. The intervention was further optimised and the testers, over a 2-week period, invited to provide feedback.

Field notes were recorded, with the discussion digitally recorded, transcribed verbatim and thematically analysed (LH). A consensus approach and agreement was sought on the development of the prototype of the intervention, in terms of content and presentation. Data analysis outlining the key components of the intervention was discussed and confirmed throughout, by the international advisory team. The web-based intervention was developed through an expert software developer- ProPeer solutions. This established company has successfully collaborated on a number of projects. Here are a few examples:- Treatment of patients suffering with Post Traumatic Stress Disorder https://youtu.be/6D5sNgjHtko Exercise Solution with Parkinson's https://drive.google.com/file/d/1j5kPbDEJ95qK1RyHCuvKFVoXwewaLYF-/view?usp=sharing .The intervention was optimised through repeated discussions and agreement between research team, software developers and patients.

Phase 2: Clinical study of the web-based intervention (Objectives 2-4)

Patients attending routine outpatient appointments at the Belfast Health and Social Care Trust (BHSCT) and Golden Jubilee National Hospital (GJNH), Clydebank will be identified and invited to participate by the Cardiologist or Heart Failure Nurse according to inclusion/exclusion criteria (See Table 1). The BHSCT and GJNH are busy tertiary centres, implanting collectively over 700 devices per annum (2019/2020). Written consent to pass on contact details to the researchers (LH or Research Assistant - RA) will be obtained. Patients will be asked to nominate a family member or caregiver, to participate in the study. Only when the patient has spoken to the family member/caregiver will their contact details be passed onto the researcher. Written information detailing the study will be provided and interested patients and family members will be offered one week to consider participation. The researcher (LH or RA) will make contact with the patient and family member to ensure both are agreeable to participate,

before obtaining written consent, baseline data is collected and 1:1 randomisation. Baseline questionnaires will be completed in all patients and caregivers recruited to the study. A convenience sample of *n*=64 patients will be randomised to the intervention and usual care, with n=64 receiving usual care alone, across Northern Ireland and Scotland. Patients and caregivers will be followed up at 3 months and 6 months' post intervention. Patients who received the Choice-ICD intervention, along with their caregivers and members of their clinical team (i.e heart failure nurse, cardiologist or cardiac physiologists) will be invited to participate in a focus group. Members of the clinical team (8-10) will be invited by the local collaborator (Dr Dixon or Prof Gardner) and if agreeable, contact details will be passed to the researcher to provide information on the study and obtain consent. Focus group will be conducted separately (Focus group 1: patients and caregivers Focus group 2: healthcare professionals) within each clinical site. Any patients, caregivers or healthcare professionals involved in Phase 1 (Co-design of the APP) will be excluded.

5: **Power calculations:**

Unpublished audit data show that in 2019/2020: 482 ICD/CRTD were implanted in NI and 250 implanted in Scotland. Given the total population size of 732 patients, we need to recruit 128 patients in total to account for an expected 10% attrition rate. This would leave a sample size of n = 114 (intervention, n = 57; control, n = 57) that enables us to estimate a recruitment rate of 50% to within a 90% confidence interval of +/- 10%, which should provide an accurate representation of the patient population. These statistics have been deemed suitable as higher precision would warrant a larger sample size, with the required resources being unsuitable for a feasibility study. Co-applicant (MD) will provide statistical support throughout. The results of the proposed study will enable the planning of a future definitive trial.

Table 1: *Eligibility Criteria*

Patient	Caregiver	Healthcare Professional
Patients with heart failure awaiting or with an ICD (no	Have contact with the patient at least 5 times per week.	Daily care of patients with heart failure and an implantable cardioverter

time restriction on implantation)		defibrillator
Aged 18 years and over	Aged 18 and over.	Willing to provide written informed consent
No cognitive impairment	Be nominated by the patient.	*Involved in the care of a patient using the Choice-ICD App*
Willing to provide written informed consent	Be physically and mentally capable of participation (self-assessment)	
	Willing to provide written informed consent.	

Exclusion criteria:

- Patients, judged by their Cardiologist as physically or mentally unsuitable to complete the study.
- Patients or caregivers lacking capacity to give consent.
- Patients who have known pregnancy
- Caregivers who's patient is unwilling to take participate

6: **Intervention:**

Patients and family members will receive the online intervention (accessed via a password protected link) and British Heart Foundation (BHF) booklet: "Implantable Cardioverter Defibrillators" (2018- HIS19/1117) or the BHF booklet only (usual care group). The eHealth intervention is theoretically driven, interactive and provides personalised information to patients and family members when and where they wish to access it. Topics include: "How does an ICD work? How will it affect my daily activities? What do I do if I experience a shock? Do I have choices ahead when my health declines?" Each topic will have a link to a printable fact sheet with a prompt card that patients can take with them to their next professional consultation. Five short (2-3 minutes) videos, involving patients, caregivers and professionals, developed with MacMillen Media, will be uploaded onto the APP, alongside animation clips and useful links to online resources (56). A discussion forum will be accessible for participants using the APP,

which will be closely moderated by the researcher, who will ensure any concerning posts or dialogue are promptly removed, and the necessary action is taken. The diary function will allow patients to record and be reminded of future appointments. This detail will not be collected, but rather is for the patient's use only. The intervention is both an informational support resource as well as a "prompt" for patients and professionals to engage in complex discussions. Patients and family members will engage with the intervention for 3 months.

Patients recruited from the Belfast Health and Social care Trust and randomised to receive the Choice -ICD intervention, will be invited to access the virtual reality (VR) enhanced intervention. Participants attending during their visit 1 or 2 to the BHSCT, will be invited to access the optional VR aspect. . The VR enhanced intervention will be carried out within Queen's University premises at the time in which focus groups have been arranged. Interested patients will receive instructions on the use of the headset (Meta Quest 3) and supervised by the researcher while it is in place The session will last for a maximum of 10 minutes, therefore minimising risk of adverse effects. A protocol to ensure the safety and tolerability of the VR session has been developed. No data will be collected from the headset. Anonymised data linked to recruitment to the VR option will be collected.

7: **Data collection & Outcome Measures:**

Descriptive data including recruitment/demand, participants' engagement/adherence with the intervention (*i.e.,* number of log-ins and screens viewed), and attrition will be collected, in line with the standards for feasibility studies (57). Patients will complete a paper copy of the validated patient reported outcome measures and short demographic questionnaire (*i.e.,* age, education, New York Heart Association (NYHA), and indication for device) at baseline. They will also complete paper versions of validated questionnaires, including the ICD concerns questionnaire (ICDC) (58), Experiences, Attitudes and Knowledge of End-of-Life issues in Implantable Cardioverter Defibrillator Questionnaire (EOL-ICDQ) (59), Beck Anxiety Inventory (BAI) (60), Brief Illness perception questionnaire (15), Florida Patient Acceptance Survey (FPAS) (61) and the Kansas City Cardiomyopathy questionnaire (KCCQ- 12) quality of life tool (62). Family members will complete the Carer Strain Index (CSI) (63). Questionnaires, at baseline, 3 and 6 months will be disseminated by the QUB researcher (LH) or research nurse

if the patient lives in Clydebank. Data will be collected month 3, including system usability scale, and again at month 6 (post intervention). Questionnaires will be disseminated in paper copy. At 3 and 6 months, a stamped addressed envelope will be provided to promote return of the questionnaires to the researcher at QUB (LH). Reasons regarding loss to follow-up will be monitored. *Primary outcome measures* are the feasibility, acceptability and usability (according to SUS) of the intervention. *Secondary outcome measures* are effect of the eHealth intervention on patients' knowledge, anxiety and device related quality of life as measured by the questionnaires. (Appendix 2)

All data collected will be monitored by the Chief Investigator to ensure ethical, legal or management issues arising are addressed promptly. The researcher (LH) alongside her team, have experience and publications in this area (LD, DF, MD, OS). Results from the study will be reported back to participants and inform the intervention in preparation for a larger future trial.

8: **Data Analysis**

Descriptive and inferential data analysis will be conducted by LH using SPSS (IDM Statistics 22), which will focus on calculating effect sizes that describe the differences between pre- and post-intervention. Sub-group analysis will be undertaken between patients implanted with an ICD for the first time and those with a pre-existing device. Qualitative data will be collected from two focus groups with patients and family members (n=20) at 3 months by the RA. Results will enrich understanding of the perceptions of patients and family members towards the intervention and its acceptability, the validated tools used and how the intervention may facilitate future deactivation conversations. Barriers and facilitators of the intervention will be openly discussed. A brief acceptability questionnaire will be completed (64). Two separate focus group with healthcare professionals (n=20) will enable an insight into their perspectives towards the intervention. Each focus group will be audio-recorded, transcribed verbatim and thematically analysed. The transcript will be independently analysed to improve rigour and consistency.

9: **Trial Monitoring:**

The study will also be monitored periodically by members of the International steering group, who will assess the progress of the study, verify adherence to the protocol and national requirements, and review the completeness, accuracy and consistency of the data.
International experts (Debra Moser, USA, Ingela Thylen, Sweden, Susanne Pedersen, Denmark), high volume device implanter and heart failure specialists (Nick McKeag, Kat McCreary) and cardiologists Stephen Pettit & Karen Hogg, two patient representatives from Patient support group and BHF representative will advise on all aspects of the study. Advice and support is also available from Dr Paul Best from the Centre of Technological Innovation, Mental health and Education (TIME).
The Research Governance Office at Queen's University Belfast, as lead sponsor, audits research studies conducted by University staff to make sure that they are being carried out in accordance with the Research Governance Framework and with the highest standards of integrity. Staff from the Research Governance Office may review the data collected in this study as part of their annual audit programme

10: **Trial Management:**

The study will be managed by an expert team of researchers and clinicians. The researcher (LH) will be supervised by Prof Donna Fitzsimons, Prof Martin Dempster Dr Olinda Santin, Dr Lana Dixon and Prof Roy Gardner to ensure research integrity and that the project is completed on time. (Gantt chart- Appendix 1)

11: **Ethics**

The protocol will be submitted to an NHS/HSC Research Ethics Commitee. Governance approval will be sought through the New HSC Approvals system New Research Approvals Service for HSC R&D in Northern Ireland | Public Health Agency - Research & Development in Northern Ireland (hscni.net) as well as approval within Golden Jubilee hospital, Clydebank and the Belfast HSC Trust. The Ethics Committees will be informed of all changes to the study

12: **Dissemination**

The results will be published in peer review journal, as well presented at national and international congresses. Patients will have the opportunity to receive a copy of the results. Dissemination will also include regional meetings with patients and healthcare professionals.

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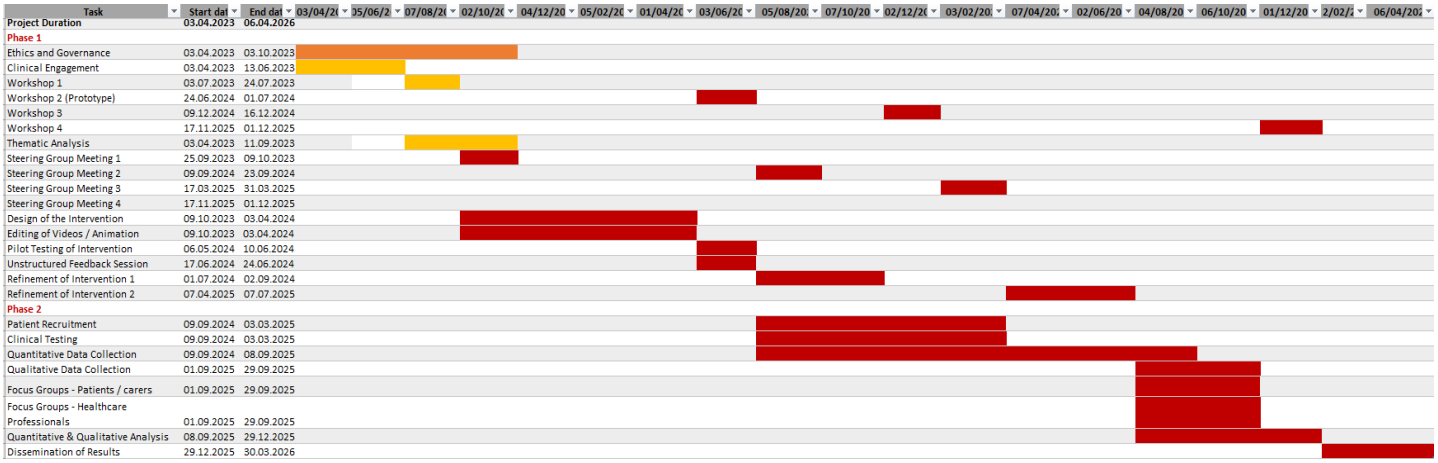
14: **Appendices**

Appendix 1: Gantt chart of the project



Task	Start dat	End dat
Project Duration	03.04.2023	06.04.2026
Phase 1		
Ethics and Governance	03.04.2023	03.10.2023
Clinical Engagement	03.04.2023	13.06.2023
Workshop 1	03.07.2023	24.07.2023
Workshop 2 (Prototype)	24.06.2024	01.07.2024
Workshop 3	09.12.2024	16.12.2024
Workshop 4	17.11.2025	01.12.2025
Thematic Analysis	03.04.2023	11.09.2023
Steering Group Meeting 1	25.09.2023	09.10.2023
Steering Group Meeting 2	09.09.2024	23.09.2024
Steering Group Meeting 3	17.03.2025	31.03.2025
Steering Group Meeting 4	17.11.2025	01.12.2025
Design of the Intervention	09.10.2023	03.04.2024
Editing of Videos / Animation	09.10.2023	03.04.2024
Pilot Testing of Intervention	06.05.2024	10.06.2024
Unstructured Feedback Session	17.06.2024	24.06.2024
Refinement of Intervention 1	01.07.2024	02.09.2024
Refinement of Intervention 2	07.04.2025	07.07.2025
Phase 2		
Patient Recruitment	09.09.2024	03.03.2025
Clinical Testing	09.09.2024	03.03.2025
Quantitative Data Collection	09.09.2024	08.09.2025
Qualitative Data Collection	01.09.2025	29.09.2025
Focus Groups - Patients / carers	01.09.2025	29.09.2025
Focus Groups - Healthcare Professionals	01.09.2025	29.09.2025
Quantitative & Qualitative Analysis	08.09.2025	29.12.2025
Dissemination of Results	29.12.2025	30.03.2026

Appendix 2:

Feasibility outcomes & Progression rules: description and target

Measure	Description of outcome	Target: a priori Criteria for success
Recruitment Rate	Proportion of eligible participants identified who participated in the study	60%
Completion of data collection measures (baseline, 3 & 6 months)	Proportion of consented participants who completed all questionnaires at baseline and post-intervention	60%
Patient engagement	Proportion of participants who completed all topics	60%
Participant acceptability	Proportion of patients accessing the intervention found it clear and understandable	80%
Intervention acceptability	Proportion of patients, caregivers and professionals who accessed the intervention and would use it again	80%

If the number is within 5% points of the progression target, a discussion would occur regarding progression to future trial within the research team