



[c h i t i n]

kite-tin

**Cross-border
Healthcare Intervention Trials
in Ireland Network**

An overview of CHITIN trials

Introduction

Health outcomes can be enhanced by evidence-based Health and Social Care (HSC) research including Health Intervention Trials (HITs), which can investigate if a new health relevant intervention is safe, better than current practice or direct resources to what works best. In Ireland, citizens cannot equitably access HSC services in the most appropriate setting to their needs and opportunity for involvement in health intervention research is confined largely to cities, close to major hospitals, universities and centres of research, which is further exacerbated by the existence of a border.

The Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN) project is supported by the EU's INTERREG VA Programme (including contribution from the Department of Health (NI) and the Health Service Executive (ROI)), funded through the European Regional Development Fund and managed by the Special EU Programmes Body, a North/South Implementation body sponsored by the Department of Finance (NI) and the Department of Public Expenditure and Reform (ROI).

The CHITIN project is a unique cross-border partnership between the Public Health Agency (PHA) in Northern Ireland (NI) and the Health Research Board (HRB) in Republic of Ireland (ROI), aiming through cross-border collaboration to develop infrastructure and deliver health intervention trials to prevent and cure illness and improve the health and wellbeing of people living in NI and the border regions of ROI by enabling them to access HSC research and services in the most appropriate setting to their needs.

The CHITIN project has enabled funding of 11 health intervention trials in the priority areas of Population Health, Primary Care and Older People's Services, Mental Health, Acute Services, Disability Services and Children's Services. The knowledge and understanding generated from these trials will impact both service users and the healthcare professionals who are delivering the services.

Interdisciplinary trial delivery teams will form a network wherein mentoring, training and skills development will be supported, resulting in enhanced capability and capacity to plan and deliver HITs, creating a legacy for future HSC research in the region.

Dr Janice Bailie, Public Health Agency

Dr Anne Cody, Health Research Board

Anticipatory Care Planning Intervention for Older Adults at Risk of Functional Decline: A Primary Care Feasibility Study



As the percentage of older adults on the island of Ireland increases, the complexity of care required to support those who choose to remain in the community has also increased. This situation can create challenges for patients, family carers, their General Practitioners (GPs), and community agencies.

The treatment and management of long-term health conditions is the greatest challenge facing health systems around the world today. A timely start in managing a patient's long-term conditions facilitates anticipatory care planning in order to meet patient wishes and needs, relieve symptoms, and prevent future symptoms and problems. Anticipatory Care Planning (ACP) through earlier identification of the needs of patients is evidenced to improve the quality of their life, to decrease the number of aggressive futile interventions and depressed mood, and even to prolong life.

A core aspect of anticipatory care is personalized care which describes a negotiated series of discussions between a patient and a health professional (perhaps with other professionals or family members also present) to clarify goals, options and preferences, and to develop an agreed plan of action based on this mutual understanding.

The aim of this health research is to determine the feasibility for a full trial

protocol to evaluate the implementation and outcomes of ACP service working with GPs to assist older adults identified as at risk for functional decline by developing a personalized support plan.

Taking part in this research are eight primary care practices, four in Northern Ireland (NI) and four in the counties of Louth and Monaghan in the Republic of Ireland (RoI) who will participate in a Randomised Controlled Trial (RCT), where GP patients who will be identified as at risk of functional decline, will be invited to participate in the trial.

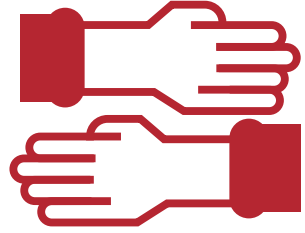
A trained Registered Nurse will visit the patient in their own home and information will be collected by a patient assessment, a patient support plan will be developed, documented and progress will be reviewed.

This health research will provide a detailed evidence-based assessment on the potential impact of the ACP intervention on patient quality of life, mental health, healthcare utilisation, costs, perception of person centred care, and reduction of the use of potentially inappropriate medication in an all-Ireland context.

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A Randomized Controlled Trial of mirror box therapy in upper limb rehabilitation with sub-acute stroke patients



Stroke can result in the loss of movement to one side of the body. This can make everyday tasks such as washing, dressing, eating, walking and household activities more difficult. To help regain movement, the brain needs to relearn how to move the arm and leg.

This health research will investigate if using Mirror Box Therapy (MBT) will enable recovery of the affected arm alongside existing occupational therapy input.

Seeing a mirror image of the arm moving is thought to trick the brain into thinking it is the affected arm that is moving, which in turn can stimulate actual movement in the arm and hand.

This research will use MBT with 180 people in hospital who have had a Stroke within the past three months. Half of the people who have had a Stroke will use the mirror box alongside their standard rehabilitation occupational therapy (OT), and half will receive standard rehabilitation OT.

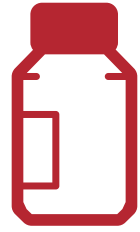
Everyone who takes part will be assessed every two weeks when they are in hospital, and 12 weeks after they get home to measure the movement in their arm.

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A randomised pilot study of a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime)



Polypharmacy (the use of multiple medicines) is considered to be a major prescribing challenge. This three-phase pilot study will seek to improve prescribing of appropriate polypharmacy in older people living in their own homes.

In Phase 1, we will interview 24 General Practitioners (GPs) across 12 practices in the Republic of Ireland (ROI) border counties and use the findings to refine the intervention package (consisting of a video and a patient recall system and which was developed in Northern Ireland).

In Phase 2, we will undertake a randomised pilot study involving 12 GP practices. Practices will be randomised to intervention (n=6) or control groups (n=6), whereby the intervention package will be tested in the intervention practices and usual care will continue in the control practices. Eligible patients will be invited to attend an appointment (at baseline and six months) with their GP, during which their medication will be reviewed and polypharmacy addressed.

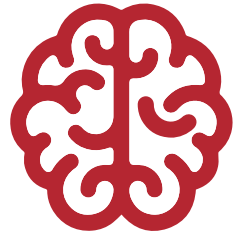
In Phase 3, a mixed methods process evaluation will be conducted to inform interpretation of findings.

The potential benefits from this health research include a refined intervention and an understanding of its implementation and expanded capacity to undertake research in the defined area through training and mentoring.

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BRAIN-Diabetes: Border Region Area lifestyle Intervention study for healthy Neurocognitive ageing in Diabetes



Diabetes mellitus (DM) is associated with an almost three-fold increased risk of Dementia in later life. The lag period between DM diagnosis and development of Dementia symptoms represents an opportunity for risk modification. A Scandinavian study showed that an intensive multi-domain lifestyle intervention programme (nutrition, exercise, cognitive stimulation and intensive vascular risk factor control) applied in older people (60-77 years) at higher risk for Dementia produced significant cognitive benefits after two years.

BRAIN-Diabetes will study the feasibility and effects of a practical lifestyle intervention programme, developed in conjunction with people with DM, on cognition in older people recently diagnosed with DM living in the border areas of Ireland.

This health research could lead to development of a practical protocol that patients can comply with which can reduce risk of cognitive decline and Dementia.

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Delivery of a habit-based intervention to overweight or obese pregnant women on the Island of Ireland: a feasibility study exploring integration into existing antenatal care pathways



More than one in two pregnant women are overweight by the time they come for their first main antenatal appointment. This research wants to look at whether it is possible to give women who are overweight or obese at the start of pregnancy a brief intervention that encourages them to develop positive food and activity habits and gain a healthy amount of weight during pregnancy.

If a mother is overweight during pregnancy, or gains too much weight during pregnancy, it puts both the short and long-term health of mum and baby at risk, for example, by increasing the risk of having a caesarean section. There is currently no help given to women who are overweight or obese at the start of pregnancy in Northern Ireland (NI) or the Republic of Ireland (ROI). We need to address the gap in healthy lifestyle advice suitable for pregnant women with something that is straightforward to deliver, yet based on scientific evidence.

‘Ten Top Tips for a Healthy Weight’ (10TT) is a simple leaflet which includes 10 healthy eating and activity habits; it has been shown in previous research to help overweight

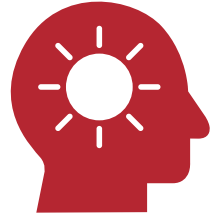
adults manage their weight over the long-term. The leaflet is unique as it is based on habit-formation. This means it builds on the idea of repeating something over and over until it becomes ‘second nature’. We will refine the 10TT leaflet to make it suitable for use during pregnancy and, alongside this we will develop a brief, flexible training course that will help healthcare staff explain the habit-based leaflet to pregnant women. We will then trial this habit-based intervention on a small scale with 80 pregnant women recruited from NI and ROI. If the intervention is acceptable to pregnant women and can be delivered in antenatal settings in NI and ROI, we will conduct a larger study to examine what effect it has on the health of pregnant women and their babies.

Ultimately, this work could result in a weight management intervention that is made widely available to pregnant women. It could, therefore, benefit pregnant women and their babies in the short and longer-term by developing lifelong healthy habits.

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Improving mental health among at-risk young people in a challenging border region



The North West of Ireland has very high rates of mental health disorders and suicide. For many people, the symptoms related to these disorders start to develop during their late teens and early 20s. A number of recent studies have documented the increasing incidence of depression, anxiety and other disorders among the student population.

Third level institutions are an excellent place to provide support and assistance to those with mental health problems but results from previous studies suggest that the current support may not be fit for purpose.

The primary goal of the current feasibility study is to determine whether a recently developed web-based intervention is effective in alleviating the symptoms of anxiety and depression.

This health research will test this, and compare the level of symptoms of depression and anxiety in students in a Randomised Controlled Trial (RCT) comparing routine campus-based counselling with treatment with the internet intervention.

The results of this research will determine whether addition of an internet intervention to the current mental health services would enhance support options and increase help-seeking among students with mental health problems.

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MY COMRADE PLUS: A pilot cluster Randomized Controlled Trial (RCT), for patients with multimorbidity, of the Multimorbidity Collaborative Medication Review and Decision Making intervention (MY COMRADE), practice based pharmacists (PBP's) or PBP's plus an adaptation of MY COMRADE



Multimorbidity is the term used when a person has more than one long-term medical condition. In general practice, patients are more likely to have multimorbidity than a single condition. How patients are treated and the evidence used to draw up guidelines for doctors are usually based on a single condition, for example, research is conducted on patients with diabetes and guidelines are developed for managing patients with diabetes. However, for patients with multimorbidity, there are many challenges, one of which is the management of multiple medications.

Internationally, people are looking for new approaches to prescribing for patients with multimorbidity, including ways to encourage patients to be more involved in managing their own condition. The aim of this health research is to test one new such approach north and south of the border in Ireland.

This health research will investigate if the MY COMRADE approach will lead to better patient care, both in the Republic of Ireland (RoI), where there are no pharmacists in General Practitioner (GP) practices and in Northern Ireland (NI), where there are pharmacists in GP practices. Before testing MY COMRADE in a large scale trial, which would take a lot of time and money, this pilot study is required to see if it is possible to use the MY COMRADE approach in practices and to see if GPs and the PBPs are willing to use this approach.

Once we know that it is possible to do this study and that practice staff are willing to use MY COMRADE approach, we can then undertake a larger trial to find out for sure if MY COMRADE can make things better for patients.

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Pragmatic Lifestyle Pregnancy and Post pregnancy Intervention for Overweight Women with Gestational Diabetes Mellitus: a Randomised Controlled Clinical Trial (PAIGE2)



Gestational Diabetes Mellitus (GDM), defined as high blood sugar levels during pregnancy, is an increasing health problem for both mothers and babies which affects up to 18% of pregnancies worldwide. Women with previous GDM are seven times more likely to develop future type 2 diabetes compared to women without GDM. There is good evidence outside of pregnancy that lifestyle change (diet and physical activity) can reduce the development of type 2 diabetes in people at risk, but there are many demands on a new mother, and weight gained during pregnancy is frequently not lost afterwards. The National Institute for Health and Care Excellence (NICE) recently highlighted that further research is urgent in this area.

We have recently completed a pilot postnatal lifestyle program for overweight women with previous GDM (PAIGE) which showed a significant 3.9 kgs weight reduction at six months among 31 women in PAIGE compared with 29 women who received usual care, supporting its clinical usefulness.

Based on feedback from the pilot study, we are now planning a definitive trial (PAIGE2) involving larger numbers of subjects, across six cross-border regions (Royal Victoria Hospital, Ulster and Antrim Area Hospitals in Northern Ireland and Letterkenny, Sligo and Drogheda Hospitals in the Republic of Ireland).

This research is a multi-component, family-based intervention customised to the postnatal period. The primary outcome is weight reduction at 12 months. If the results of PAIGE2 are positive, they could have major implications for population health and be readily translated into routine clinical practice.

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The feasibility of a walking intervention to increase activity and reduce sedentary behaviour in people with serious mental illness



People who have a serious mental illness can sometimes die earlier in life than those without. The medications people take for their mental illness combined with an unhealthy lifestyle (e.g. not enough physical activity and too much sitting) can contribute to this. Walking is a good way to increase physical activity in the general population and may help people with serious mental illness to be more active.

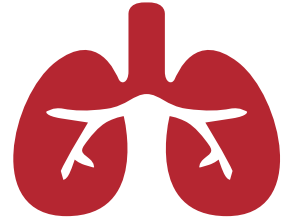
This study is a feasibility Randomised Controlled Trial (RCT) which will compare different ways of increasing physical activity and reducing sedentary behaviour in people with serious mental illness. We will invite people with schizophrenia, psychosis, bipolar disorder or major depression to take part in our study. The participants will be randomly split into two groups. One group will take part in a 17-week walking programme and the other group will receive information on the benefits of walking.

If people with serious mental illness move more and sit less we would expect their physical and mental health to improve. If we show this health research is feasible, we can plan to complete a large study to investigate the effectiveness of our walking programme in people with serious mental illness.

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The use of digital technologies to enhance adherence and inhaler technique and guide treatment among patients with severe asthma



The INhaler Compliance Assessment (INCA) device, developed by researchers at the Royal College of Surgeons Ireland (RCSI) and Trinity College Dublin (TCD), uses digital signals from inhalers to identify a patient's inhaler technique and adherence to obtain a complete understanding of their inhaler use over time.

The INCA SUN (Symptomatic UNcontrolled asthma) study is a prospective randomised multicentre study to optimise the management of symptomatic asthma patients. It aims to demonstrate that information provided from the INCA technology along with peak flow and environmental data can be integrated and used to guide asthma nurse training and physician management more effectively than current standard care.

The ultimate aim is to give patients with severe asthma greater control over their condition and to improve their quality of life.

This health research will recruit 220 patients mostly from severe asthma clinics in academic teaching hospitals, however, clinicians and patients in border regions experience reduced access to research due to geographical location or distance for travel and the CHITIN call allows these barriers to be addressed by deploying the INCA SUN study to border county/regional areas.

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The Walking In Schools (WISH) Trial: a cross-border trial to evaluate a walking intervention in adolescent girls



The transition from primary to second-level education represents a time when physical inactivity increases, especially in adolescent girls. School-based activities that increase opportunities for physical activity are needed, particularly for those left out of other sporting activities because of the competitive selection process for school teams, and for types of activity that can be easily maintained into adulthood, such as walking.

This research will assess the effectiveness of a low-cost school-based, peer-led walking intervention in increasing physical activity in adolescent girls when delivered across the school year in a fully-powered trial in schools across Northern Ireland (NI) and the border region of the Republic of Ireland (RoI).

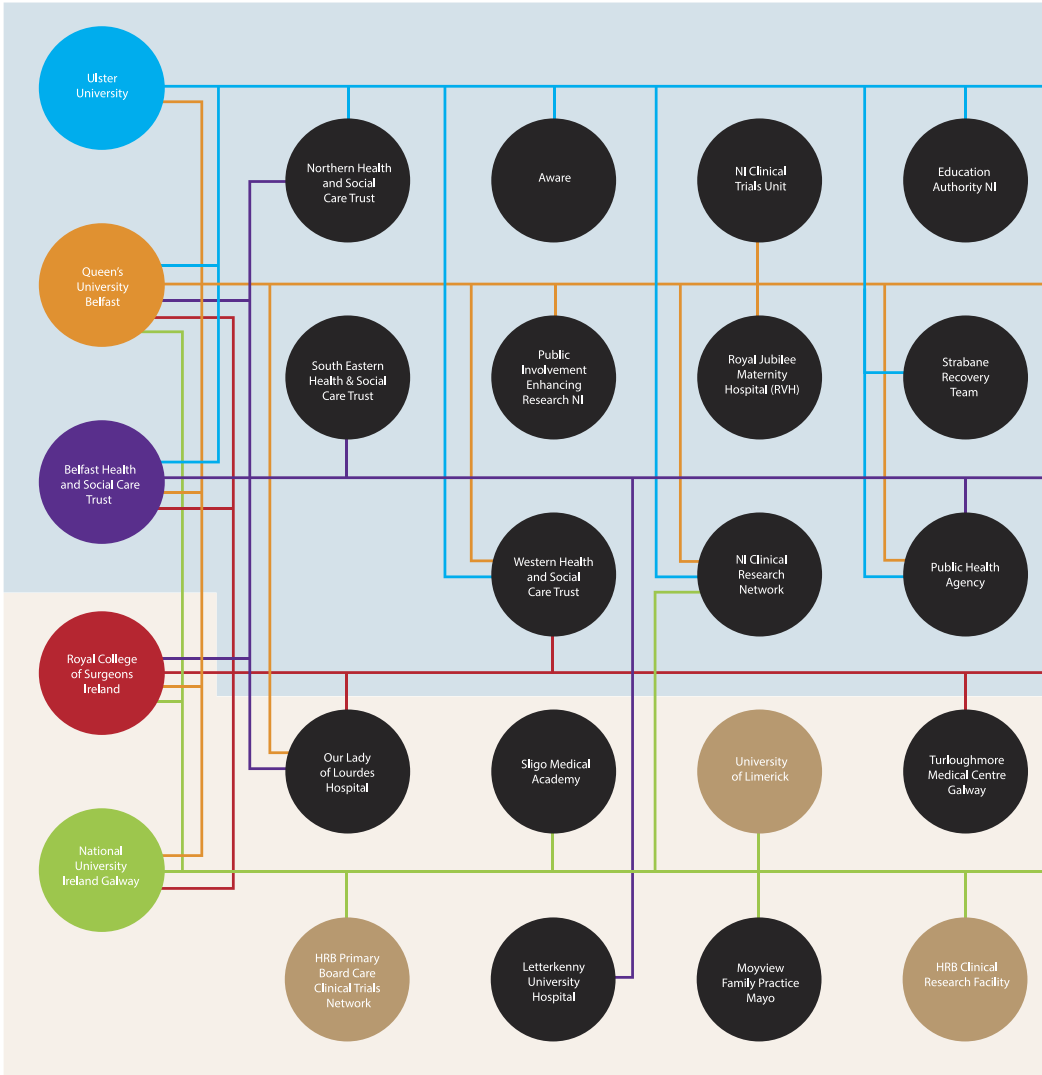
Intervention participants will be encouraged to take part in short peer-led walks delivered across the school day in or around the school grounds, led by older pupils (aged 16-18 years) trained as walk leaders. Using physical activity monitors (accelerometers) we will objectively assess the effectiveness of the intervention at increasing total activity and reducing sedentary behaviours among pupils at the mid-point and end of the school year.

If the intervention increases physical activity, it would benefit adolescent girls in the defined target area and have potential for adoption by schools across the entire island of Ireland resulting in sustainable, long-term, positive impacts on child population health.

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This is a diagram of the CHITIN network

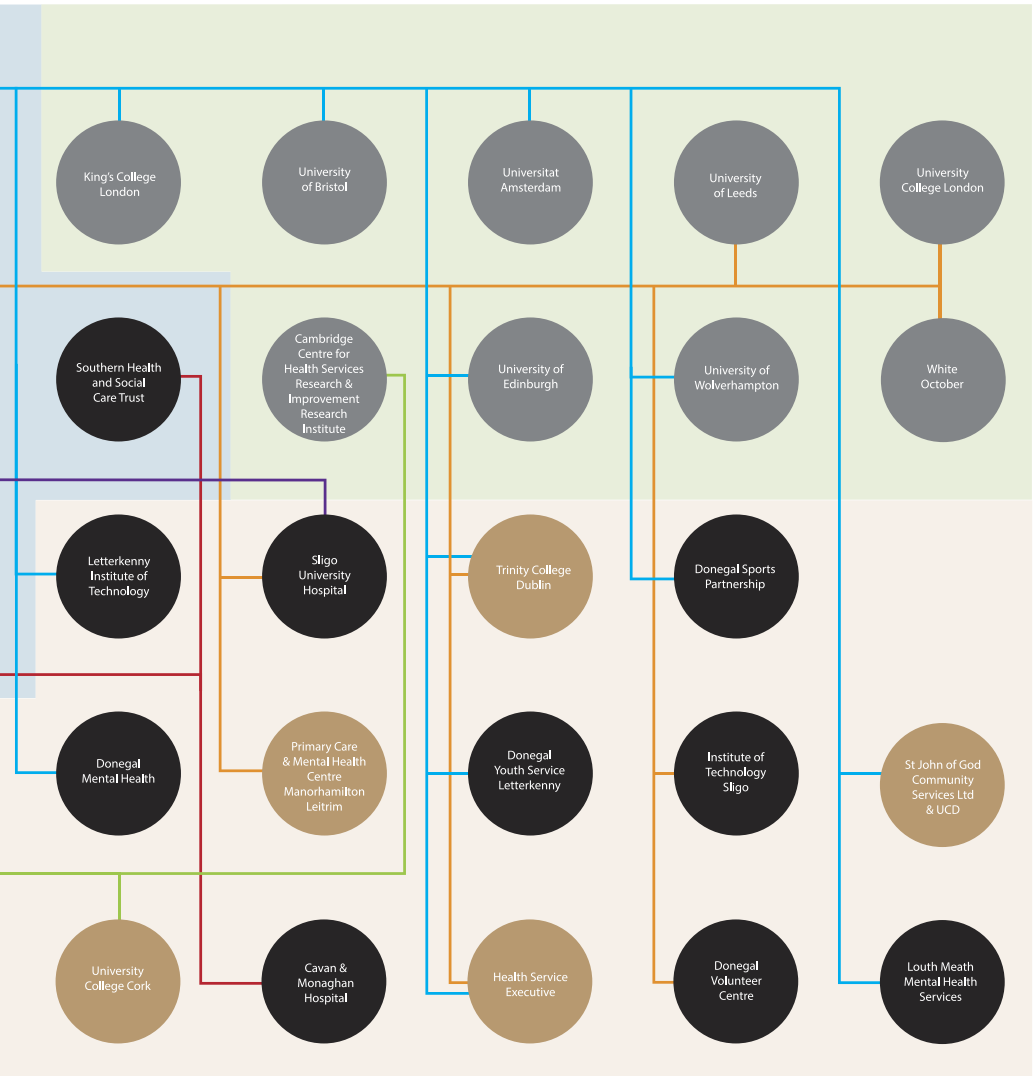


Key:

- NI partners
- ROI partners
- Partners outside Defined Area
- Defined Area - NI + six border counties

The six border county areas are:

Cavan, Donegal, Leitrim, Louth, Monaghan and Sligo



For further information on CHITIN:

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