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Cross-border

Healthcare Intervention Trials
in Ireland Network

PAIGE2 – Pragmatic Lifestyle Pregnancy and Post Pregnancy Intervention for Overweight Women with Gestational Diabetes Mellitus.

Interreg 
Northern Ireland - Ireland - Scotland
European Regional Development Fund

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Overview

- What is GDM – why is it important?
- The PAIGE study – what they did
 - what worked
 - what did they find out
 - what next
- The PAIGE2 study
- PAIGE2 & CHITIN
- PAIGE2 & MLB



What is GDM?

Gestational diabetes mellitus (GDM) is defined as glucose intolerance with onset or first recognition during pregnancy

GDM develops during pregnancy, like other types of diabetes, it affects how your cells use sugar, which can lead to high blood sugar, this in turn can affect pregnancy outcomes for mother and infant.

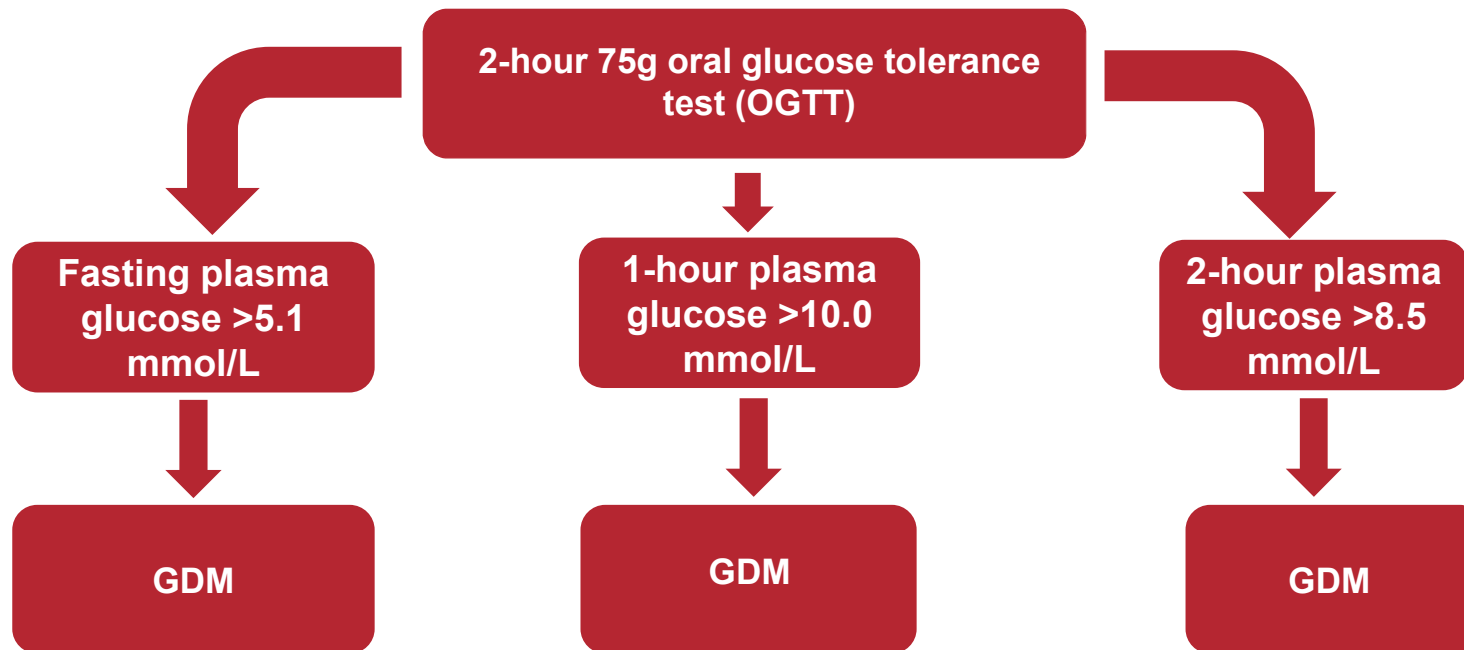
It's not fully understood why some women develop gestational diabetes, however alterations in glucose metabolism are a normal physiological adaptation that occurs during pregnancy.

During pregnancy, the placenta, which connects the fetus to the maternal blood supply, produces high levels of hormones.

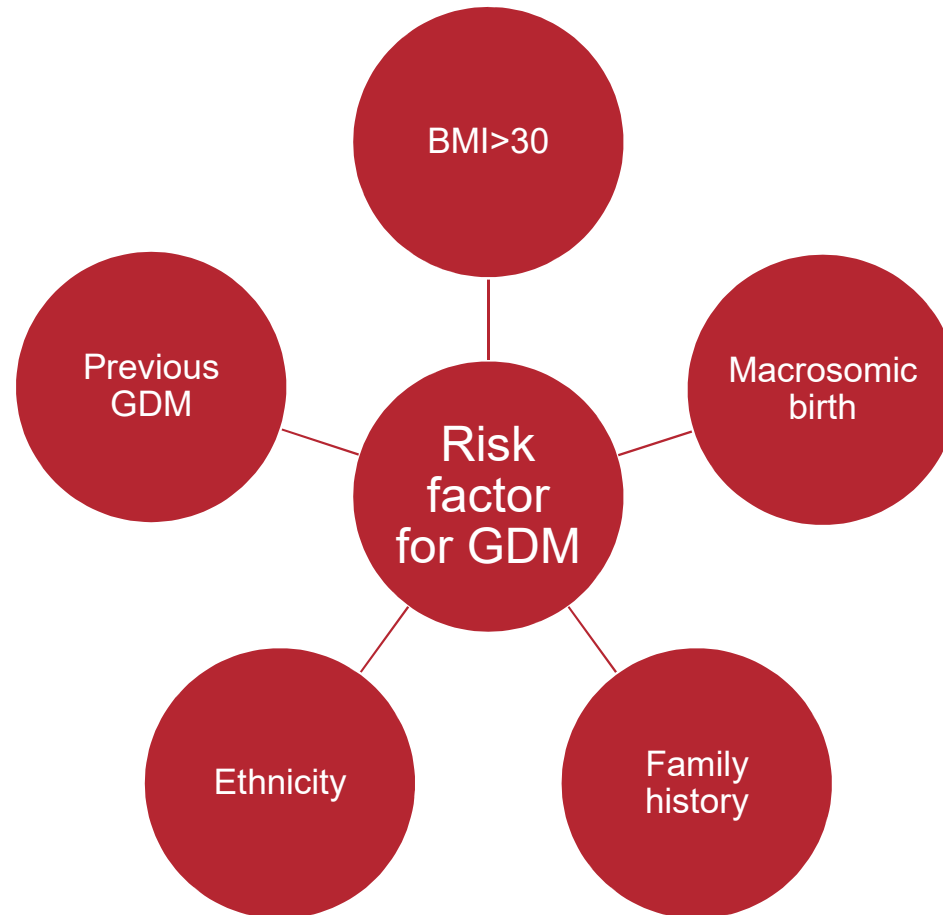
As the baby grows, the placenta produces more and more insulin-counteracting hormones.

Diagnosing GDM

GDM is diagnosed by administering a 2-hour 75g oral glucose tolerance test (OGTT).



Screening – occurs between 24 and 28 weeks of gestation



Risks

- Large for gestational age birthweight/macrosomia
- Need for assisted delivery (Caesarean Section)
- 50% more likely to develop GDM in future pregnancy
- High risk of developing type 2 diabetes in the future
- Childhood and adult obesity in offspring

Prevention

Eat healthy foods. Choose foods high in fibre and low in fat and calories. Focus on fruits, vegetables and whole grains.

Keep active. Exercising before and during pregnancy can help protect from developing gestational diabetes. Aim for 30 minutes of moderate activity on most days of the week. Take a brisk daily walk. Cycle. Swim.

Lose excess pounds before pregnancy. Weight loss during pregnancy is not recommended. But for women planning to get pregnant, losing extra weight beforehand may help reduce the risk of developing GDM

PAIGE

Background - GDM is associated with a 7-fold ↑ risk of type 2 diabetes

High gestational weight gain and postpartum weight retention are established predictors of long-term obesity.

Aim - To determine the impact of a postnatal lifestyle intervention program for overweight women with previous gestational diabetes mellitus (PAIGE).

Methods

- Women with a BMI >25 & previous GDM were recruited at 6 weeks postpartum to participate in a multicenter randomized controlled trial
- The intervention comprised of a 1-hour educational program, a free 3-month referral to a commercial weight management organization (Slimming World), a pedometer, and structured telephone and text support, in addition to usual care.
- The control group received standard care only. The primary outcome was weight loss at 6 months.

Results

Sixty women were randomized (29 intervention; 31 control) in two centers.

The intervention group demonstrated significant weight loss at 6 months after randomization compared with the control group: mean \pm SD, 3.9 \pm 6 7.0 kg vs 0.7 \pm 3.8 kg ($P = 0.02$).

With respect to well-being measures, bodily pain was significantly reduced in the intervention group ($P = 0.007$).

Results

Table 1. Baseline Characteristics of Study Participants (N = 60)

Characteristic	Intervention (n = 29)	Control (n = 31)
Age, y	34.2 (4.3)	33.2 (5.3)
Weight, kg	89.6 (16.8)	90.2 (16.4)
BMI, kg/m ²	34.1 (6.3)	33.6 (5.4)
Waist circumference, cm	103.7 (11.2)	105.8 (12.1)
Hip circumference, cm	116.8 (12.9)	116.2 (11.4)
Fat mass, kg	39.7 (12.8)	39.1 (11.9)
Fat free mass, kg	49.9 (5.7)	51.2 (6.5)
White ethnicity, n (%)	25 (86.0)	26 (84.0)
Employed, n (%)	22 (76.0)	20 (65.0)
Education, y	17.1 (3.0)	16.3 (3.1)
Married/cohabiting, n (%)	24 (83.0)	27 (87.0)
Smoker, n (%)	3 (10.0)	4 (13.0)
Parity, mean number of pregnancies	2.5 (1.2)	2.3 (1.2)
Primiparous, n (%)	5 (17.0)	8 (26.0)
Breastfeeding, n (%)	7 (24.0)	14 (45.0)
Diet-only treatment of GDM in most recent pregnancy, n (%)	8 (28.0)	9 (29.0)
Time since delivery, wk ^a	9.8 (3.2)	9.3 (2.2)
Fasting plasma glucose, mmol/L	5.05 (0.56)	5.15 (0.66)
2-h plasma glucose after OGTT, mmol/L	6.09 (1.76)	6.14 (2.28)
Fasting serum insulin, mU/L ^b	11.7 (6.3–19.1)	12.6 (7.7–13.9)
2-h serum insulin, mU/L ^c	41.1 (18.2–56.4)	33.3 (16.9–46.4)
HbA1c, mmol/mol ^d	35.0 (4.2)	37.4 (4.1)
LDL cholesterol, mmol/L ^e	3.0 (0.7)	3.4 (0.9)
HDL cholesterol, mmol/L ^f	1.5 (0.4)	1.5 (0.3)
Cholesterol, mmol/L ^f	5.3 (0.8)	5.6 (1.1)
Triglycerides, mmol/L ^f	1.4 (0.9–2.1)	1.3 (0.7–1.6)

Data are mean (SD), median (interquartile range), or n (%).

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Results

Table 2. Group Differences in Anthropometric and Blood Glucose Measurements From Baseline to 6 Months After Intervention

Variable	Intervention (n = 20)			Control (n = 25)			Intervention Effect ^a	
	Baseline	6 Mo After Intervention	Change	Baseline	6 Mo After Intervention	Change	Estimate (95% CI)	P Value (Two-Tailed)
Weight, kg ^b	91.6 (17.3)	87.7 (17.8)	-3.9 (7.0)	90.6 (16.4)	91.2 (17.8)	0.7(3.9)	-4.5 (-8.1 to -0.9)	0.02
BMI, kg/m ^{2c}	34.8 (6.7)	33.4 (6.9)	-1.4 (2.7)	33.5 (5.6)	33.8 (6.2)	0.2 (1.4)	-1.6 (-3.0 to -0.2)	0.03
Waist circumference, cm ^d	106.2 (10.1)	103.3 (12.0)	-2.9 (6.7)	106.8 (13.3)	108.4 (12.4)	1.7 (5.3)	-4.5 (-8.4 to -0.7)	0.02
Hip circumference, cm ^d	117.9 (13.8)	115.8 (14.4)	-2.1 (6.3)	115.9 (11.0)	114.9 (10.6)	-1.0 (4.5)	-1.2 (-4.7 to 2.4)	0.51
Fat mass, kg ^d	41.0 (12.8)	38.4 (14.5)	-2.6 (7.5)	37.9 (11.5)	38.0 (12.7)	0.1 (5.7)	-2.7 (-6.9 to 1.6)	0.22
Fat free mass, kg ^d	51.5 (4.9)	50.4 (6.9)	-1.0 (6.1)	51.7 (6.9)	51.9 (6.4)	0.1 (5.4)	-1.2 (-4.8 to 2.5)	0.52
Fasting plasma glucose, mmol/L ^e	5.1 (0.5)	5.3 (0.9)	0.2 (0.5)	5.0 (0.4)	5.1 (0.5)	0.1 (0.4)	0.1 (-0.2 to 0.4)	0.49
2-h plasma glucose after OGTT, mmol/L ^f	5.9 (1.8)	6.3 (2.5)	0.4 (1.8)	5.7 (1.4)	5.6 (0.9)	-0.1 (0.9)	0.5 (-0.4 to 1.4)	0.27
Fasting serum insulin, mU/L ^g	14.9 (8.1)	15.5 (7.5)	0.6 (4.8)	10.1 (4.1)	14.5 (8.1)	4.4 (7.0)	-1.8 (-6.3 to 2.7)	0.43

Data are mean (SD).

Results

Table 3. Results From the SF-12v2™ Health Survey Questionnaire and the Exercise Self-Efficacy Questionnaire at 6 Months in the Intervention and Control Groups

Variable	Intervention (n = 20)			Control (n = 25)			Intervention Effect ^a	
	Baseline	6 Mo After Intervention	Change	Baseline	6 Mo After Intervention	Change	Estimate (95% CI)	P Value (Two-Tailed)
SF-12v2™ Health Survey								
General health ^b	51.6 (20.1)	46.1 (21.8)	-5.5 (25.3)	57.5 (23.3)	55.2 (24.6)	-2.3 (22.3)	-6.3 (-19.5 to 7.0)	0.35
Mental health ^c	56.9 (18.8)	55.0 (10.3)	-1.9 (16.4)	60.7 (10.9)	57.1 (12.4)	-3.8 (13.8)	-0.9 (-7.6 to 5.8)	0.79
Physical functioning ^d	85.0 (22.1)	94.1 (10.2)	9.1 (18.9)	86.4 (21.4)	79.3 (23.0)	-7.0 (22.6)	15.3 (5.1 to 25.5)	0.004
Bodily pain ^e	55.4 (31.3)	5.4 (10.6)	-50.0 (31.0)	57.7 (27.7)	36.5 (37.7)	-21.2 (38.0)	-30.6 (-51.9 to -9.3)	0.007
Vitality ^f	45.8 (23.1)	50.0 (21.0)	4.2 (32.4)	51.1 (17.6)	52.2 (21.2)	1.1 (26.6)	-2.2 (-15.9 to 11.6)	0.75
Role emotional ^g	84.2 (19.9)	82.2 (22.9)	-2.0 (23.7)	85.3 (21.5)	88.0 (21.1)	2.7 (21.3)	-5.3 (-17.7 to 7.2)	0.40
Social functioning ^g	86.8 (22.6)	81.6 (27.4)	-5.3 (28.5)	82.6 (23.2)	81.5 (28.4)	-1.1 (33.3)	-1.3 (-18.5 to 15.9)	0.88
Role physical ^h	71.7 (23.5)	85.5 (15.7)	13.8 (26.6)	78.0 (25.3)	82.5 (25.5)	4.5 (28.6)	4.6 (-8.5 to 17.8)	0.48
Exercise self-efficacy								
Sticking to it ⁱ	3.4 (0.8)	3.4 (0.8)	-0.1 (0.6)	3.3 (0.6)	2.9 (0.8)	-0.4 (0.8)	0.4 (0.0-0.8)	0.07
Making time to exercise ^h	3.7 (0.7)	3.5 (0.7)	-0.3 (0.9)	3.6 (0.7)	3.3 (0.8)	-0.3 (0.9)	0.1 (-0.3 to 0.6)	0.52

Data are mean (SD).

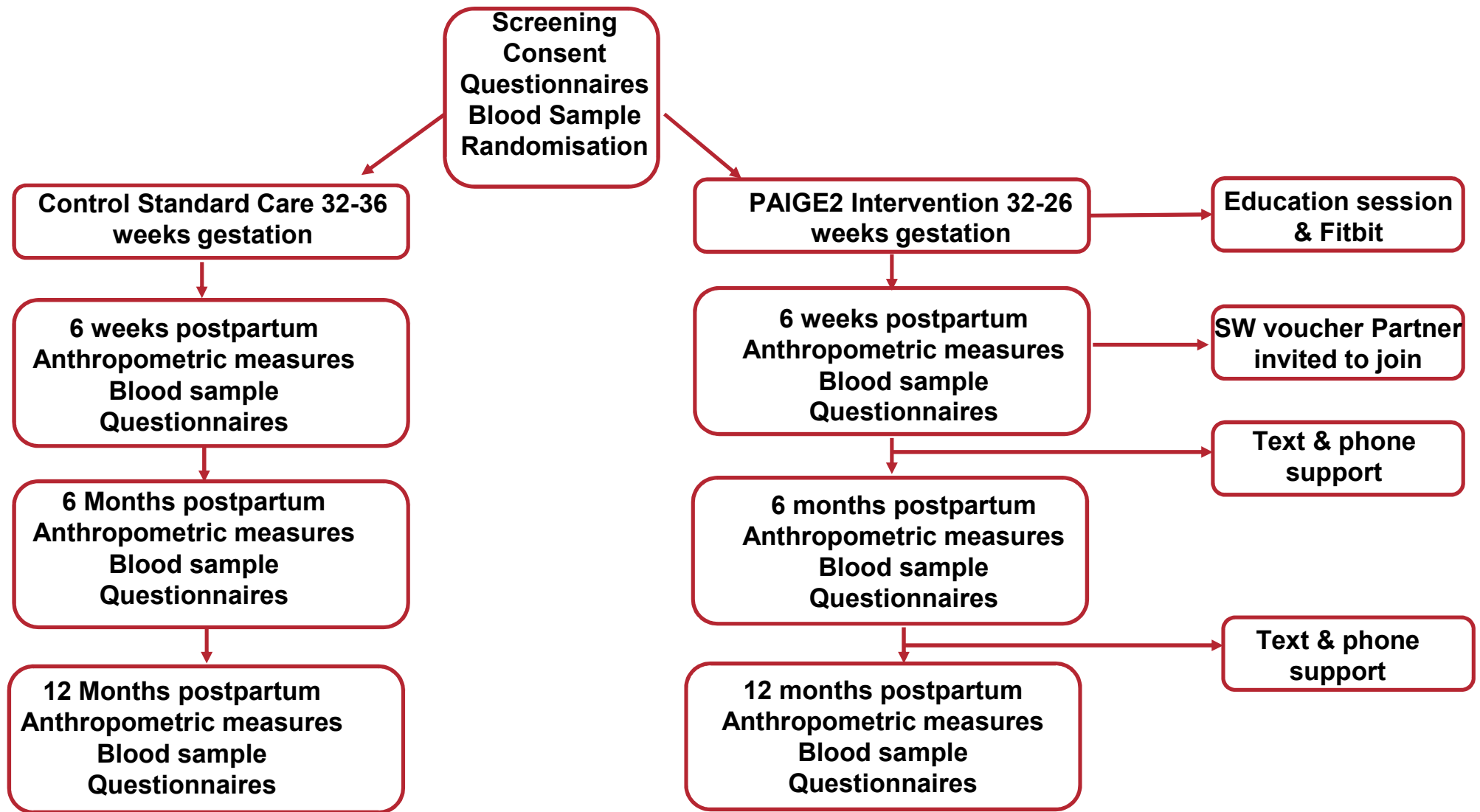
What worked?

- Education session and accompanying booklet
- Structured text and phone support
- CMWO – for those who registered

What didn't?

- Timing of recruitment
- Pedometer
- Lack of family support

PAIGE2 – Pragmatic Lifestyle Pregnancy and Post Pregnancy Intervention for Overweight Women with Gestational Diabetes Mellitus.



Screening
Consent
Questionnaires
Randomisation
Blood sample



Control Standard Care 32-36 weeks gestation

6 weeks postpartum
Anthropometric measures
Blood sample
Questionnaires

6 Months postpartum
Anthropometric measures
Blood sample
Questionnaires



12 Months postpartum
Anthropometric measures
Blood sample
Questionnaires



PAIGE2 Intervention 32-26 weeks gestation

6 weeks postpartum
Anthropometric measures
Blood sample
Questionnaires

6 months postpartum
Anthropometric measures
Blood sample
Questionnaires



12 months postpartum
Anthropometric measures
Blood sample
Questionnaires



Education session
Fitbit



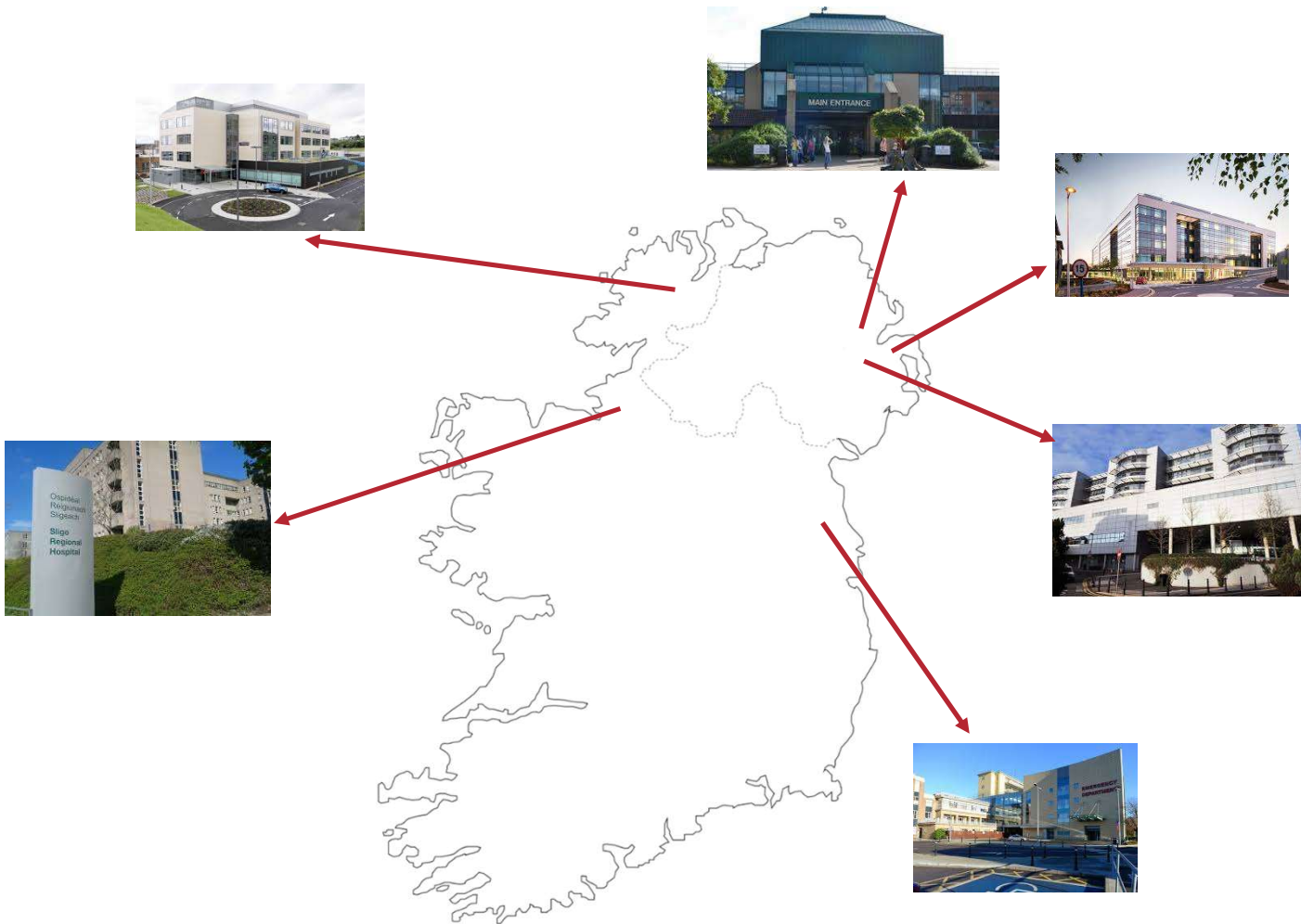
SW voucher Partner invited to join

Text & phone support



Text & phone support





- Sligo University Hospital
- Letterkenny University Hospital
- Antrim Area Hospital
- Ulster Hospital
- Royal Victoria Hospital
- Our Lady of Lourdes Hospital, Drogheda,



Making Life Better 2012–2023 is the ten-year public health strategic framework. The framework provides direction for policies and actions to improve the health and wellbeing of people in Northern Ireland.

‘Achieving a healthier Northern Ireland will hinge on what we do together, through policy and practice, to influence the key factors which impact on life chances and choices and ultimately on health and wellbeing’

Thank you to all our collaborators

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Thank you

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