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All Wales Diabetes Prevention Programme: outcome evaluation

Submission date
07/10/2024

Recruitment status
No longer recruiting

Registration date
06/02/2025

Overall study status
Completed

Last Edited
06/02/2025

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Research suggests that modest interventions (based on diet and physical activity lifestyle modifications) can reduce progression to type 2 diabetes (T2D) by more than 50% for those identified as pre-diabetic. The Welsh Government have allocated funding to Public Health Wales to roll out an All Wales Diabetes Prevention Programme (AWDPP) throughout primary care clusters (PCCs) in Wales. Phased roll-out of the programme commenced in June 2022, with roll-out limited to 2-3 clusters per Health Board per annum, where each cluster is approximately 50-75k in population, varying in size across rural-urban areas. This study aims to evaluate the efforts of the AWDPP and determine its effect on reducing the risk of T2D amongst those who participate in the intervention.

Who can participate?
Individuals within participating primary care clusters in Wales, who have had an HbA1c level between 42-47 mmol/mol within the last 3 months, will be invited to attend the AWDPP intervention.

What does the study involve?
Participants who attend the AWDPP intervention between June 2022 to June 2023 will be included in the study, as part of the 'treatment group'. 'Comparison group' participants will be drawn from existing data held within those practices that have delivered the intervention in Wales. All participants must have had a baseline HbA1c 42-47 mmol/mol, with HbA1c undertaken at follow-up (around 12 months). A change in HbA1c, from baseline and follow-up, will be the primary focus. This change will be compared across the two study groups (treatment & comparison). The comparison group will not have received the AWDPP intervention, as the AWDPP would not have been 'live' during the period in which they presented with a baseline HbA1c of 42-47 mmol/mol.

What are the possible benefits and risks of participating?
There are many benefits for participants of the AWDPP intervention. They will obtain knowledge towards the risks of T2D and what changes they can make to prevent themselves developing the

chronic condition. Individuals may also be referred to other services, as to aid their journey in reducing their risk of ill health. There are no obvious risks associated with participating in the study.

Where is the study run from?
This study is run by Public Health Wales' Research & Evaluation Team, with statistical advice provided by Swansea University's Diabetes Research Group.

When is the study starting and how long is it expected to run for?
The first intervention delivered by the AWDPP took place in June 2022. This study focuses on the outcomes related to participation in the AWDPP intervention from June 2022 to June 2023. Data will be collected from April 2022 to September 2024.

Who is funding the study?
Funding for this study has been provided by the AWDPP, at the request from the Welsh Government that evaluation is embedded in the design and delivery of the programme.

Who is the main contact?
james.bailey@wales.nhs.uk or charlotte.grey2@wales.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Evaluating the outcome of the All Wales Diabetes Prevention Programme (AWDPP): a stepped wedge approach

Acronym
AWDPP

Study objectives
1. Statistically significant difference in HbA1c from baseline to follow-up, associated with intervention
2. Lower incidence of Type 2 Diabetes at follow-up, when compared to usual care

Ethics approval required
Ethics approval not required

Ethics approval(s)
This is a service evaluation study, which does not require ethics approval under Wale’s law.

Primary study design
Interventional

Study design
Non-randomised stepped wedge study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of incidence of type 2 diabetes amongst those identified as 'pre-diabetic'.

Interventions
The All Wales Diabetes Prevention Programme (AWDPP) intervention was delivered by healthcare professionals throughout Wales between June 2022 and June 2023.

The design is non-randomisation. The design has been pragmatically designed around the live implementation of the AWDPP throughout Wales within the last 2 years. Study arms - comparison group is derived from existing primary care health records data before a primary care practice began delivering the AWDPP. No treatment is given to this group, as the intention is to understand the counterfactual (i.e., what is the normal progression in HbA1c, for somebody who is prediabetic, before the inception of AWDPP). Treatment group - they are offered a brief 30-minute consultation with a Health Care Support worker, to discuss their relative risk of developing type 2 diabetes, and what behaviours they may adopt to reduce this risk. As part of NICE guidance, and common practice within primary care, individuals deemed pre-diabetic will routinely be recalled for a repeat HbA1c blood test, 12 months post the last - this routinely collected blood test is the follow-up measure used in both arms of the study.

Intervention Type
Behavioural

Primary outcome(s)
Hemoglobin A1c (HbA1c) measured using a blood test at baseline and follow-up (around 12 months)

Key secondary outcome(s)
Incidence of type 2 diabetes measured using HbA1c results at baseline and follow-up (around 12 months)

Completion date

01/09/2024

Eligibility

Key inclusion criteria
1. HbA1c 42-47 mmol/mol within the last 3 months (from a search undertaken in primary care health records by HCSW)
2. Aged 18 years and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Key exclusion criteria
1. Ever diagnosed with type 1 or 2 diabetes
2. BMI < 20 kg/m2
3. Current prescription of Metformin
4. Receiving palliative care
5. Pregnant
6. Artificially fed

Date of first enrolment
29/06/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
All Wales
All Wales
All Wales
United Kingdom
All Wales

Sponsor information

Organisation
Public Health Wales

ROR
https://ror.org/00265c946

Funder(s)

Funder type
Government

Funder Name
Public Health Wales

Alternative Name(s)
Iechyd Cyhoeddus Cymru, Public Health Wales NHS Trust, PHW

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the data that is contained within has the potential to be identifiable and

includes sensitive information such as health records. Data generated within this study are stored within the Secure Anonymised Information Linkage (SAIL) Databank, which is not a publicly available repository.

IPD sharing plan summary

Not expected to be made available