

# MWIK - AI-powered decision support tool for diabetes clinicians

<b>Submission date</b> 11/01/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 09/02/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

MyWay IQ (MWIK) is an electronic software application that provides advice (clinical decision support) around the diagnosis and treatment of patients with diabetes and is delivered as part of the MyWay Clinical (MWC) and MyWay Diabetes (MWD) platforms. MWC is designed for healthcare professional (HCP) use, whilst MWD is designed for people with diabetes. MWIK can also be used within other systems that are used in patient care (Electronic Health care Records (EHR)). MWIK predicts the type of diabetes and the risk of complications and provides advice about the best medications to use for individual patients. This study will assess how easy it is to use the system (usability), how useful the system is to users, and how safe the advice it supplies is. This information will help the system developers register the product with the Medicines and Healthcare products Regulatory Agency (MHRA), who are responsible for regulating medical devices, including software applications.

### Who can participate?

Healthcare professionals involved in the care of people with diabetes.

### What does the study involve?

Participants will be asked to use the system within their normal diabetes clinics, and provide feedback via questionnaires and interviews.

### What are the possible benefits and risks of participating?

Participants may find that the system allows them to make a more informed decision about an individual patient's medical management (e.g. the type of medicine to prescribe). If the system results in improved clinical care, then this will benefit patients and the wider population of people with diabetes. Participants may find that the system does not help with their clinical decision-making or is in some way intrusive during the normal clinical consultation. These are the sort of issues that the researchers will learn about through the feedback that they gather. There is a risk that the system does not work as expected, however, there is a process in place to check the system is working well before it is used in the clinic.

### Where is the study run from?

University of Dundee (UK)

When is the study starting and how long is it expected to run for?  
August 2021 to July 2024

Who is funding the study?  
National Institute for Health Research (NIHR) (UK)

Who is the main contact?  
Dr Nicholas Conway  
nicholas.conway@nhs.scot

## Contact information

**Type(s)**  
Principal Investigator

**Contact name**  
Dr Nicholas Conway

**Contact details**  
c/o MWDH Ltd  
MacKenzie Building  
Kirsty Semple Way  
Dundee  
United Kingdom  
DD2 4BF  
+44 (0)1382 660111  
nicholas.conway@nhs.scot

## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**  
305267

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
NIHR - AI\_AWARD02234, IRAS 305267

## Study information

**Scientific Title**  
MyWay IQ (MWIQ) - safety and efficacy testing of a diagnosis and precision medicine tool for diabetes management

**Acronym**

## AI Award MWIQ

### Study objectives

Current study hypotheses as of 18/05/2023:

Primary hypothesis: MyWay IQ (MWIQ) is safe within both simulated and real-world clinical environments.

Secondary hypotheses: MWIQ is usable; MWIQ is useful; MWIQ has an impact on clinician prescribing and diagnosing; MWIQ has an impact on patient metabolic outcomes.

Previous study hypotheses:

Primary hypothesis: MyDiabetes IQ (MDIQ) is safe within both simulated and real-world clinical environments.

Secondary hypotheses: MDIQ is usable; MDIQ is useful; MDIQ has an impact on clinician prescribing and diagnosing; MDIQ has an impact on patient metabolic outcomes.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

Approved 08/01/2024, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; None available; gram.nosres@nhs.scot), ref: 23/NS/0134

### Study design

Open-label single-arm single-site feasibility study

### Primary study design

Interventional

### Secondary study design

Feasibility study

### Study setting(s)

GP practice

### Study type(s)

Prevention

### Participant information sheet

See study outputs table

### Health condition(s) or problem(s) studied

Diabetes

### Interventions

Current interventions as of 18/05/2023:

This feasibility investigation will determine whether an AI-powered clinical decision support tool for diabetes is (a) safe; (b) usable; (c) alters clinician prescribing or diagnostic behaviour and (d) leads to any changes in metabolic outcomes for patients under the care of clinicians using the

tool. This qualitative evaluation will assess usability/safety; examine data relating to clinician behaviour; and analyse routinely-collected clinical patient data.

1. Qualitative evaluation of usability/engagement and safety of MWIQ (online questionnaires, qualitative interviews, system logs, navigation data). Run charts will be used to record usability and safety issues
2. Assess the impact of MWIQ on clinical workflow (descriptive statistics of prescribing /diagnostic data)
3. Measure clinical outcomes (descriptive statistics of metabolic outcomes, including BP and HbA1c, compared with background patient data)

#### Previous interventions:

This feasibility investigation will determine whether an AI-powered clinical decision support tool for diabetes is (a) safe; (b) usable; (c) alters clinician prescribing or diagnostic behaviour and (d) leads to any changes in metabolic outcomes for patients under the care of clinicians using the tool. This qualitative evaluation will assess usability/safety; examine data relating to clinician behaviour; and analyse routinely-collected clinical patient data.

1. Qualitative evaluation of usability/engagement and safety of MDIQ (online questionnaires, qualitative interviews, system logs, navigation data). Run charts will be used to record usability and safety issues
2. Assess the impact of MDIQ on clinical workflow (descriptive statistics of prescribing /diagnostic data)
3. Measure clinical outcomes (descriptive statistics of metabolic outcomes, including BP and HbA1c, compared with background patient data)

### Intervention Type

Mixed

### Primary outcome measure

1. System safety: frequency of user-flagged safety concerns measured using a combination of patient-level questionnaires, weekly questionnaires and unsolicited issues highlighted by participants. Specific measures include:
  - 1.1. Number of risks identified by patient-level questionnaires (interim and cumulative total), expressed as a percentage of the number of patient records reviewed
  - 1.2. Clinical safety score recorded with a weekly questionnaire for each of the MWIQ features (diabetes sub-type predictor, diabetes drug response predictor, and diabetes complications predictor) as well as overall experience. The score will be recorded on a 5-point Likert scale and the distribution of scores will be expressed as a percentage of responses received.
  - 1.3. Clinical plausibility score recorded with a weekly questionnaire for each of the MWIQ features (diabetes sub-type predictor, diabetes drug response predictor, and diabetes complications predictor) as well as overall experience. The score will be recorded on a 5-point Likert scale and the distribution of scores will express as a percentage of responses received. Free text comments will be analysed for emergent themes

All outcomes measured at the end of the study period in addition to monthly interim analysis, as part of the Data and Safety Monitoring Board (DSMB) process

### Secondary outcome measures

1. System usability measured using a combination of weekly questionnaires, qualitative data (free text questionnaire comments and semi-structured interviews) and validated questionnaire

(system usability scale). Specific measures include:

1.1. Overall ease of use recorded on a 5-point Likert scale. The distribution of scores will be expressed as a percentage of responses received.

1.2. Free text comments and semi-structured interview transcripts will be analysed for emergent themes.

1.3. System Usability Scale to be administered at the end of the study period.

2. System usefulness measured using a combination of weekly questionnaires and qualitative data (free text questionnaire comments and semi-structured interviews). Specific measures include:

2.1. Clinical usefulness score recorded with a weekly questionnaire for each of the MWIQ features (diabetes sub-type predictor, diabetes drug response predictor, and diabetes complications predictor) as well as overall experience. The score will be recorded on a 5-point Likert scale and the distribution of scores will be expressed as a percentage of responses received.

3. System impact measured using a combination of routinely collected clinical data, system navigation data and weekly questionnaire data. Specific measures include:

3.1. Number of patients with the following care processes recorded within the past 12 months: HbA1c, blood pressure (BP), serum cholesterol, serum creatinine, urinary albumin, foot screening, Body Mass Index (BMI) and smoking status. The number of each will be expressed as a percentage of the total number of people with diabetes seen by participants within the study period.

3.2. Number of patients meeting the following treatment targets: HbA1c <58 mmol/mol, blood pressure ≤140/80 mmHg, cholesterol <5 mmol/l, as well as the number meeting all three targets. The number of each will be expressed as a percentage of the total number of people with diabetes seen by participants within the study period.

3.3. Number of patients with reclassified diabetes diagnosis, expressed as a percentage of the total number of people with diabetes seen by participants within the study period.

3.4. Subjective assessment of system impact recorded on a 5-point Likert scale. The distribution of scores will be expressed as a percentage of responses received.

3.5. Free text comments submitted via questionnaire analysed for emergent themes

3.6. Number of participant interactions with the system and time spent within the system (cumulative total and per patient)

All outcomes measured at the end of the study period in addition to monthly interim analysis, as part of the Data and Safety Monitoring Board (DSMB) process

### **Overall study start date**

02/08/2021

### **Completion date**

31/07/2024

## **Eligibility**

### **Key inclusion criteria**

For healthcare professionals (HCPs), the inclusion criteria are:

1. Male or female

2. 18 years or over

3. GPs involved in the care of people with diabetes within Greater Manchester

4. Able to provide informed consent

Patient data from four GP practices will be utilised - data will be from patients who are:

1. Male or female
2. Aged 18 years or over
3. Diagnosis of diabetes (any type)

**Participant type(s)**

Patient, Health professional

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

2 clinician participants per practice x 8 GP practices = 16 clinicians participants plus 3 validator participants (diabetes specialists) who will validate MDIQ decisions = total 19 participants (all healthcare professionals)

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

08/01/2024

**Date of final enrolment**

28/07/2024

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Northenden Group Practice**

489 Palatine Road

Northenden

Manchester

United Kingdom

M22 4DH

**Study participating centre**

**Cornbrook Medical Practice**  
204 City Road  
Hulme  
Manchester  
United Kingdom  
M15 4EA

**Study participating centre**  
**Peel Hall Medical Practice**  
Forum Health  
Simonsway  
Wythenshawe  
Manchester  
United Kingdom  
M22 5RX

**Study participating centre**  
**Manchester Medical**  
Moss Side Health Centre  
Monton Street  
Moss Side  
Manchester  
United Kingdom  
M14 4GP

**Study participating centre**  
**The Park Medical Practice**  
434 Altrincham Road  
Wythenshawe  
Manchester  
United Kingdom  
M23 9AB

**Study participating centre**  
**Brooklands Medical Practice**  
594 Altrincham Road  
Wythenshawe  
Manchester  
United Kingdom  
M23 9JH

**Study participating centre**  
**Northern Moor Medical Practice**  
216 Wythenshawe Road  
Northern Moor  
Manchester  
United Kingdom  
M23 0PH

**Study participating centre**  
**Woodlands Medical Practice**  
9 Maple Road  
Brooklands  
Manchester  
United Kingdom  
M23 9RL

## **Sponsor information**

**Organisation**  
MyWay Digital Health Ltd

**Sponsor details**  
MacKenzie Building  
Kirsty Semple Way  
Dundee  
Scotland  
United Kingdom  
DD2 4BF  
+44 (0)7904 154101  
debbie.wake@mwdh.co.uk

**Sponsor type**  
Industry

**Website**  
<https://www.mywaydigitalhealth.co.uk>

## **Funder(s)**

**Funder type**  
Government



**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

1. The Clinical Investigation Plan is drafted but not yet published and will be made available at the appropriate point, given the commercially sensitive nature of the project effort
2. Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

31/01/2025

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Clinician Experts version 1.0	20/01/2022	20/01/2022	No	Yes
<a href="#">Participant information sheet</a>	Clinician Participants version 1.0	20/01/2022	20/01/2022	No	Yes