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MWIQ - AI-powered decision support tool for diabetes clinicians

Submission date	Recruitment status	[X] Prospectively registered
11/01/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/01/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/07/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
MyWay IQ (MWIQ) 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. MWIQ can also be used within other systems that are used in patient care (Electronic Health care Records (EHR)). MWIQ 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

Integrated Research Application System (IRAS)
305267

Protocol serial number
NIHR - AI_AWARD02234

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

Primary study design
Interventional

Study design
Open-label single-arm single-site feasibility study

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s)
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

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)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
6

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
United Kingdom

England

Study participating centre
Northenden Group Practice
489 Palatine Road
Northenden
Manchester
England
M22 4DH

Study participating centre
Cornbrook Medical Practice
204 City Road
Hulme
Manchester
England
M15 4EA

Study participating centre
Peel Hall Medical Practice
Forum Health
Simonsway

Wythenshawe
Manchester
England
M22 5RX

Study participating centre
Manchester Medical
Moss Side Health Centre
Monton Street
Moss Side
Manchester
England
M14 4GP

Study participating centre
The Park Medical Practice
434 Altrincham Road
Wythenshawe
Manchester
England
M23 9AB

Study participating centre
Brooklands Medical Practice
594 Altrincham Road
Wythenshawe
Manchester
England
M23 9JH

Study participating centre
Northern Moor Medical Practice
216 Wythenshawe Road
Northern Moor
Manchester
England
M23 0PH

Study participating centre
Woodlands Medical Practice
9 Maple Road

Brooklands
Manchester
England
M23 9RL

Sponsor information

Organisation
MyWay Digital Health Ltd

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

Individual participant data (IPD) sharing plan

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?
Protocol article		05/10/2025	06/10/2025	Yes	No

Participant information sheet	Clinician Experts version 1.0	20/01/2022	20/01/2022	No	Yes
Participant information sheet	Clinician Participants version 1.0	20/01/2022	20/01/2022	No	Yes