Full Study title

A feasibility study evaluating the impact of differing completion rates of a face-to-face diabetes self-management education programme on patient reported outcome measures.

Short Study Title or Acronym

Differing completion rates of **DIABETES** education on **P**atient **R**eported **O**utcomes (DIABETES-PRO study)

Protocol Version number and date

Version: 1.1.0

Date: 27.03.24

Research Reference Numbers

IRAS Number:	337691
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Student Number:	201781864

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I confirm that I will make the findings of the study publicly available through publication or other dissemination tools without unnecessary delay and that an honest, accurate and transparent account of the study will be given. Any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: **Date:**

.....

......./...../.....

Name (please print):

Mrs Karen Jennings-Wilding

Position:

Senior Clinical Research Governance Manager

Chief Investigator:

Signature: ..... **Date:**

Name: (please print):

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Sponsor	The University of Liverpool is the research Sponsor for this Study. It is recognised that as an employee of the University the Chief Investigator has been delegated specific duties, as detailed in the Sponsorship Approval letter. For further information regarding the sponsorship conditions, please contact: Mrs Karen Jennings-Wilding Senior Clinical Research Governance Manager Sponsor@liverpool.ac.uk
Key Protocol Contributors	Dr Kevin Hardy* **Email**: kevin.hardy@sthk.nhs.uk Professor Greg Irving* **Email**: irvingg@edgehill.ac.uk
Committees	This research proposal will be submitted to IRAS for independent ethical opinion by the Health Research Authority. University of Liverpool Committee on Research Ethics** (online ethical approval process completed – confirmed that IRAS approval required)

*CV in appendix 1. ** University of Liverpool research ethics application project ID 13707.

Study Summary

Study Design	Quantitative feasibility study
Study Participants	People with type 2 diabetes mellitus
Planned Size of Sample (if applicable)	120 people with type 2 diabetes. Participants will be randomised across four groups, each with 30 participants.
Follow up duration (if applicable)	4 months
Planned Study Period	This is educational research which is being undertaken to fulfil the requirements of a 3-year full time PhD with University of Liverpool commencing November 2023. GANNT chart detailing timetable of research activities in appendix

	1.
Research Question/Aim(s)	Aims Using a quantitative approach this feasibility study aims to explore if patients who attend minimal aspects (10%) of diabetes self-management education (DSME) programmes gain clinically significant improvements in ability to self-care compared to those who do not attend. If the nationally accepted 60 % completion rate is as effective as 100% completion, and if Research question 1. What is the impact of differing completion rates of DSME programmes on ability to self-care (primary outcome), diabetes distress and health related quality of life in type 2 diabetes.

Abstract

Background: Structured diabetes self-management education (DSME) is internationally recommended for all people with newly diagnosed type 2 diabetes and is designed to support patients in self-managing their condition and prevent associated long-term complications. DSME is proven to be as effective as pharmacotherapy in preventing diabetes associated morbidity and premature mortality but attendance at both a national and local level remains poor. Local records suggest that of those that start DSME (9%) only 12.6% complete the programme. Attendance at DSME is currently benchmarked as having completed a registration form and had at least one active engagement with a programmes content, with 'completion' measured against ≥60% completion despite landmark trials reporting outcomes based on the full completion of a programme. Little is known, of the effectiveness of DSME on the psychological and emotional health of people with diabetes who complete less than the full DSME programme.

Aim: This feasibility study will test the impact of differing completion rates of a face-to-face DSME programme on patient reported outcomes measuring self-care, diabetes distress and quality of life in people with type 2 diabetes.

Methods: Using a quantitative approach, a single centre, randomised feasibility study will be conducted, aiming to recruit 120 eligible people with type 2 diabetes due to attend a secondary care diabetes clinic in the Northwest UK for specialist support, education and advice. Participants will be randomised into one of four groups: Group 1 will receive a full DSME programme, Group 2 will receive 60%, Group 3 will receive 10% and Group 4 will have delayed education. Normal clinical care will continue. Preliminary outcomes (psychometric questionnaire scores measuring ability to self-care, diabetes distress and health related quality of life) will be evaluated at baseline and 3-4 months post-intervention. Measures of feasibility (eligibility, recruitment and retention rates) will be

reported.

Original contribution to knowledge: Whilst the current literature evidences the clear benefits for people with type 2 diabetes attending DSME programmes, there is minimal understanding of the benefits of partial DSME completion on a person's ability to self-care despite national consensus accepting 60% attendance as 'completed'. The proposed research aims to test the feasibility of conducting a full randomised control trial to evaluate the effectiveness of DSME programmes on psychometric outcomes with differing completion rates.

Lay Summary

Type 2 diabetes accounts for 90% of all diabetes diagnoses. Without proper care, type 2 diabetes can result in complications such as stroke, heart disease, kidney disease, eye disease and nerve damage. On average, a person with diabetes spends less than three hours a year with a healthcare professional meaning patients must manage their own diabetes almost 100% of the time. Diabetes self-management education plays an important role in helping people stay healthy, live well, and avoid life threatening complications and is proven to be effective in lowering blood glucose levels and preventing health problems later in life. Despite an increased awareness of the importance of education for people with type 2 diabetes, attendance at education programmes remains very poor with little to no change over the past decade.

Many things can prevent attendance or completion of education programmes, including physical and mental health issues, reduced finances, work and childcare commitments, location of education programmes and lack of information on programme content or availability. Little is known on the effectiveness of only attending part of an education programme on a person's ability to self-care.

This study will examine the impact of differing completion rates of diabetes self-management education programmes on a person's self-care skills. The psychological impact of not completing a diabetes self-management education programme is unknown and a better understanding of this could help tailor future education offers for people with type 2 diabetes. This is a smaller study to see if a larger project is feasible in the future.

Funding and Support in Kind

FUNDER(S)	FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN
Department of Endocrinology and Diabetes, St Helens Hospital, Mersey and West Lancashire Teaching Hospitals NHS Trust.	Funded clinical research fellow post and PhD fees at University of Liverpool. Postage costs for patient information sheets to patients

Roles and Responsibilities of Study Sponsor and Funder

The sponsor of this study is University of Liverpool where the researcher is currently registered on her full-time

3-yr PhD. The University of Liverpool is a member of the prestigious Russell Group of UK research intensive institutions and is internationally recognised with 91% of its research being ranked as world-leading and internationally excellent in the latest Research Excellence Framework. As the study sponsor, the University of Liverpool is responsible for the initiation and management of the research and takes primary responsibility for ensuring that the design of the study meets appropriate standards.

The funder is the Diabetes Centre, St Helens Hospital, Mersey and West Lancashire Teaching Hospitals NHS Trust who will provide the working environment and resources for the clinical research fellow post to which the researcher is employed.

Service user involvement

The DIABETES-PRO study design and justification have been discussed with a service user living with diabetes. Having completed previous education programmes they were shocked by the low number that attend DSME programmes and that a record of 'attended' required minimal engagement with a programme, or that a patient is classes as 'completed' following engagement with >60% of a programme. The service user was reassured that all patients would be offered a full education programme at the end of the study and thought the offer of a home visit or telephone appointment to reduce the burden on patients to attend an additional appointment at the end of the study (follow up visit) was important.

Templates from the Health Research Authority (HRA) have been adopted for use in this study to ensure that participant information sheets and consent forms are easy to read and contain the required information to support participants in making an informed choice.

Peer review

Peer review has been completed and submitted to the sponsor. Copies of peer review feedback is included in Appendix 1. The internal peer reviewer (Consultant Physician/Diabetologist) and external peer reviewer (Physiotherapy Lecturer and Researcher) both approved the study. Comments are summarised below, with accompanying amendments.

1. Clarify the role of the researcher in supporting participants (minor). Section 6.2 Study processes updated and Section 9 Adverse events updated to include table 5.

Protocol Contributors

Author of the protocol: Gemma Lewis

Supervision / advice: Dr Kevin Hardy, Professor John Wilding, Professor Greg Irving.

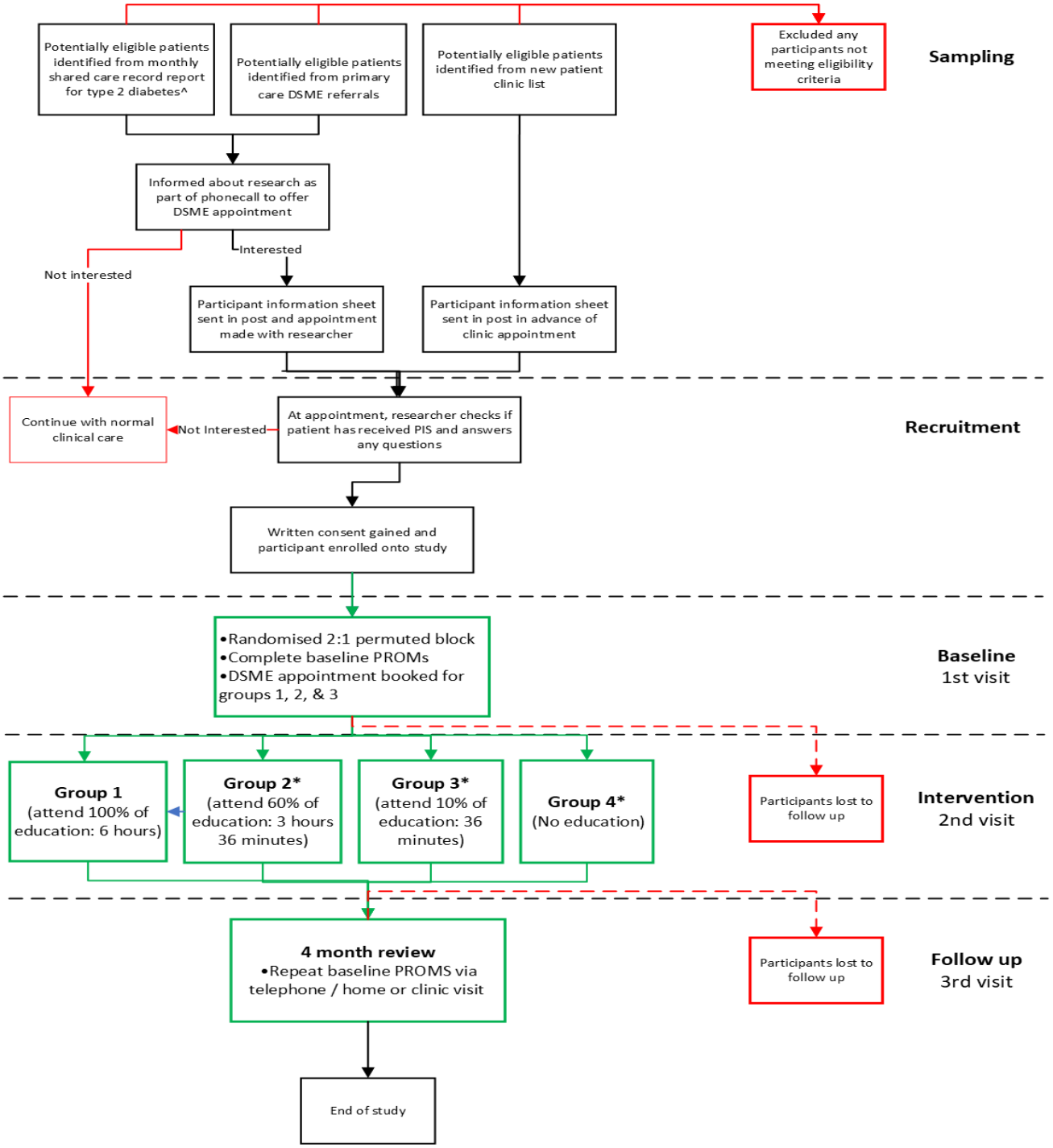
The PhD student will undertake this research as part of a research PhD at the University of Liverpool. The study sponsor (University of Liverpool) and funder (Mersey and West Lancashire Teaching Hospitals NHS Trust) will

control the final decision on study design, conduct, data analysis and interpretation , manuscript writing and dissemination of results.

James Lind Alliance top 10 priorities for type 2 diabetes have informed the aims and objectives for this research protocol (1).

Key Words: type 2 diabetes mellitus; patient education as topic; patient reported outcome measures; health education;

Study Flow Chart



^People newly diagnosed with type 2 diabetes in primary care receive a snowmed code recording their diagnosis on EMIS, this is reported via a shared care report which is used to offer DSME by the specialist diabetes centre which is also the DSME provider.
*At the end of the study participants in groups 2, 3 and 4 will be offered a full DSME programme.

Figure 1: Study flow chart

Glossary of Abbreviations

HRA	Health Research Authority
REC	Research Ethics Committee
PIS	Participant Information Sheet
DSME	Diabetes Self-Management Education
PRO	Patient Reported Outcome
PROM	Patient Reported Outcome Measure
MCID	Minimal Clinically Important Difference
QISMET	Quality Institute for Self-Management Education and Training
HCPC	Health and Care Professions Council
HEA	Higher Education Academy
NICE	National Institute of Clinical Excellence

Contents

INTRODUCTION

This protocol describes 'A feasibility study evaluating the impact of differing completion rates of a face-to-face diabetes self-management education programme on patient reported outcome measures and provides information about procedures for entering participants, study procedures, safety reporting and governance requirements. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study following receipt of required approvals.

Queries relating to this study should be referred in the first instance to the researcher or chief investigator.

This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act 2018 and the UK general data protection regulation as amended from time to time and any successor legislation in the UK and any other directly applicable regulation relating to data protection and privacy as well as any other regulatory requirements as appropriate.

BACKGROUND

Diabetes is a complex condition leading to increased disability and premature mortality; 7000 excess deaths in the United Kingdom in 2022 (2). The International Diabetes Federation (IDF) estimate 537 million people are living with diabetes around the world (3) of whom approximately 4.3 million reside in the UK (4). Over 90% of diagnoses are attributed to type 2 diabetes with an increased prevalence in areas with high levels of deprivation, poor access to healthcare, poorer housing, reduced finances, and lower levels of educational attainment (5). Presentation and disease progression of type 2 diabetes are heterogeneous, which can lead to delayed diagnosis, multiple abnormalities, and varying susceptibility to complications (6). Complications are often classified as either microvascular, such as retinopathy, neuropathy, and nephropathy, or macrovascular including cardiovascular, cerebrovascular, and peripheral vascular disease (7).

Diabetes prevalence in the UK has generally increased year on year since 2010/11 from less than 5% (8) to more than 7.3% in 2022/23 (9). Public Health England identified the most common causes of morbidity in 2019 according to global burden of disease, as measured by age standardised years lived with disability (YLDs) per 100,000 population, with diabetes accounting for the second main cause in males (figure 2), and the seventh main cause of morbidity in females (figure 3) (8). The YLD rate for diabetes mellitus increased significantly between 1990 and 2019 (males >2.3, females >2.2) (8). In 2019 the USA had the highest burden of all cause morbidity in both males and females followed by England (and the UK), while Japan had the lowest, England had the highest rate of morbidity for diabetes in males and second highest for diabetes in females (8). Whilst mortality specifically linked to diabetes has decreased (10), emergency admissions have increased more rapidly in areas of high deprivation when compared to those in the least deprived quintiles (11). Increased incidence of diabetes is associated with Black and Asian ethnicity (12,13) and lower socio-economic status [17,18] which is associated with poorer outcomes and poorer compliance with diabetes treatments [19], including engagement with DSME [20] and a significantly greater mortality rate (14).

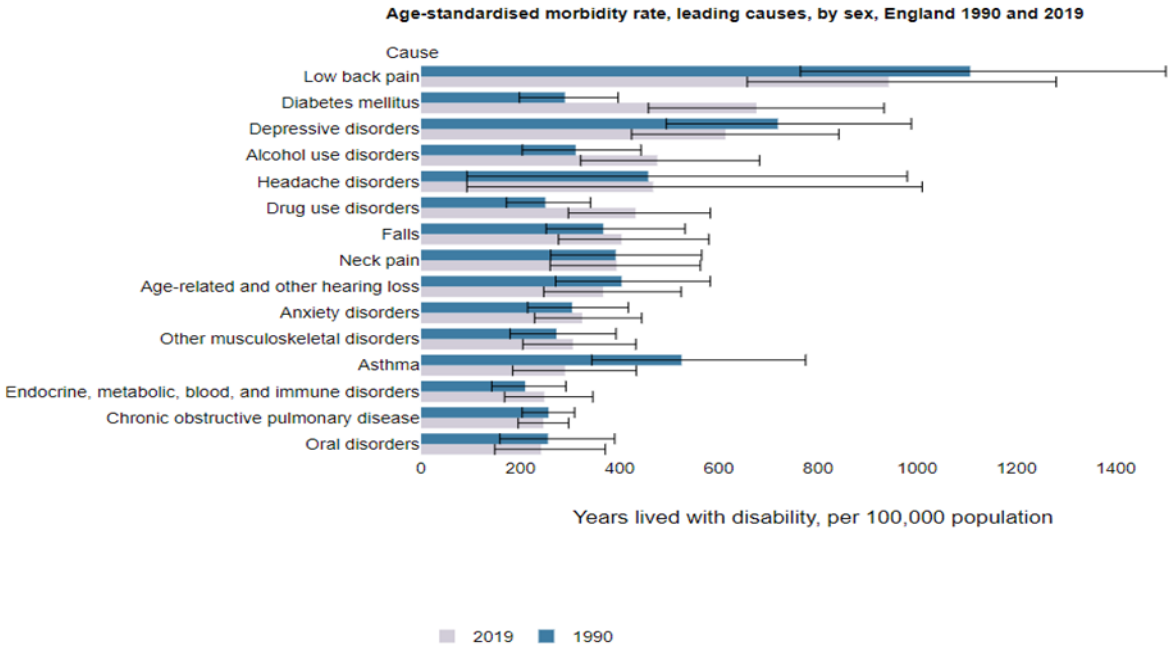


Figure 2: Male common causes of morbidity in England 2019 (8)

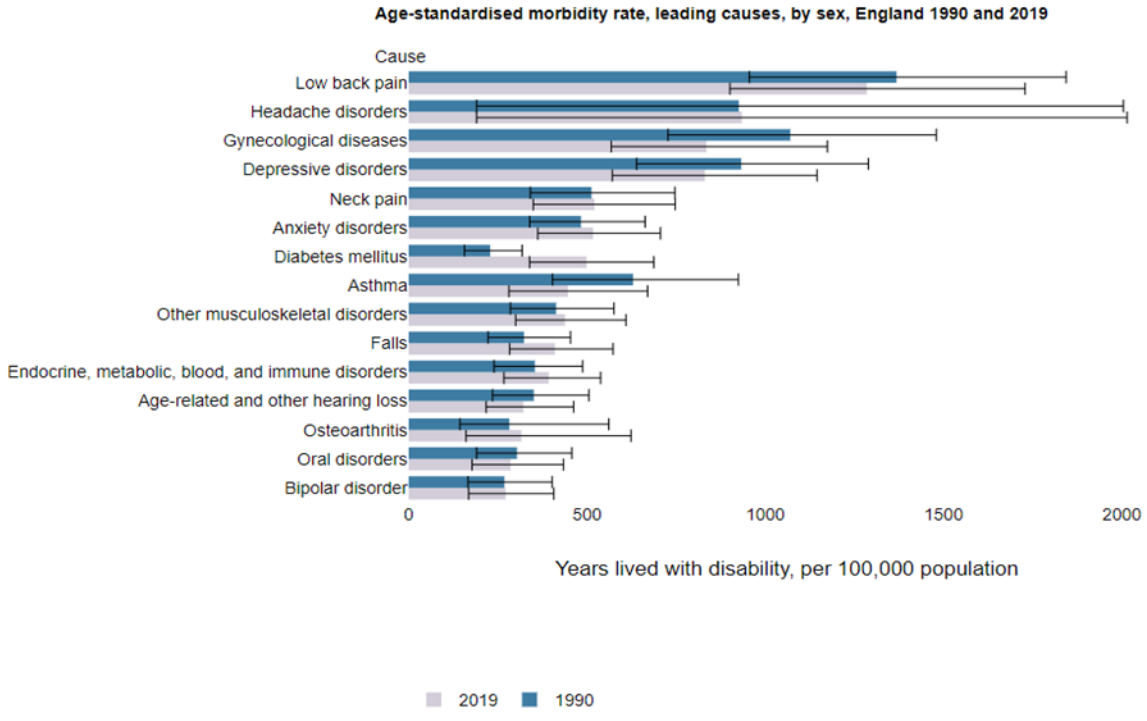


Figure 3: Female common causes of morbidity in England 2019 (8)

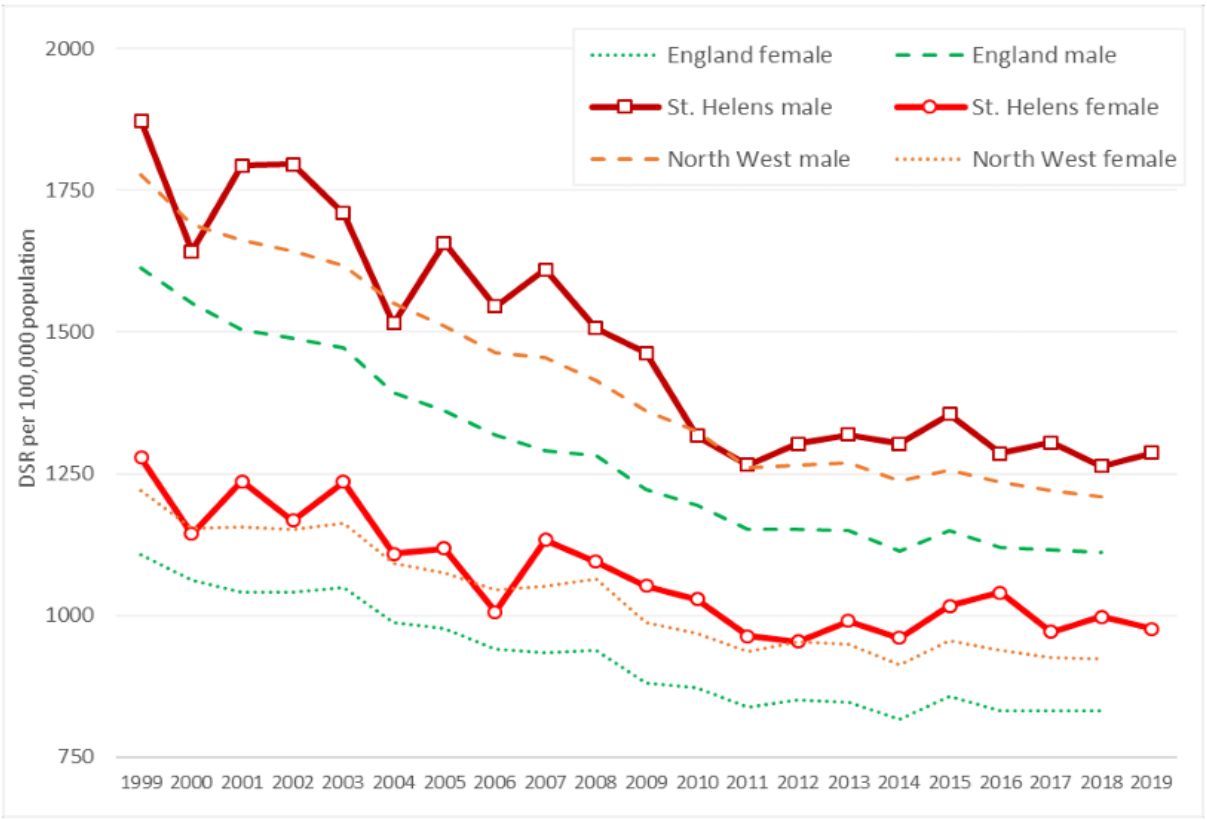
NICE recommends DSME is offered at the point of diagnosis and annually thereafter for people with type 2 diabetes (15). Despite this, uptake of DSME remains poor (table 1) (9) with a discord between offered and attended figures at a local and national level with evidence suggesting DSME is equally as important as pharmacotherapy in the effective management of type 2 diabetes (15–17). Negative perceptions of education remain an obstacle to adult learning and the uptake of DSME [22] despite a joint consensus by the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) (18) and NICE (15) all considering DSME as the foundation for successful management of diabetes, and for avoidance of associated metabolic co-morbidities and hospitalisation (19).

Table 1: DSME figures of offer and attended within 12 months of diagnosis (9)

DSME within 12 months of diagnosis	St Helens %	England %
Offered	68.9	71.0
Attended	9.1	7.0

The National Diabetes Audit suggests 71% of people with type 2 diabetes are offered DSME, with an average attendance rate of 7%. Local records suggest that of those that start DSME (9%) only 12.6% complete the programme (20), with those in a lower socioeconomic group harder to reach despite often needing the intervention the most (21). Multiple studies have demonstrated poor attrition rates across DSME programmes meaning patients frequently do not receive the required number of hours or content (21,22). NHS England (23) and the Center for Disease Control and Prevention (24) currently benchmark DSME attendance as completed a registration form and had at least one active engagement with a programmes content, with completion measured against ≥60% despite landmark trials (23,25–27) reporting outcomes based on full completion of a programme. Evidence suggests the reasons for non-attendance and non-completion of DSME are multifactorial (28–31), with patients living in areas of high deprivation more likely to decline DSME programmes (30,32,33).

The borough of St Helens has a legacy of poor health linked with deprivation and the town's industrial past. St Helens is ranked as the 26th most deprived local authority in England, its relative position having deteriorated since 2015 with almost 25% of residents living in the 10% most deprived neighbourhoods in the country (34). St Helens has widespread health deprivation with a higher-than-average diabetes prevalence of 9.2% (14,935 individuals) (20), versus 7.3% in England (35). Despite improvements in mortality rates over the last 20 years the borough's mortality rate remains higher than the national average as seen in figure 4 (36), with two thirds of adults recorded as overweight or obese, 1 in 5 adults are physically inactive and less than 50% eat the recommended '5 a day' (37).



*Source: NHS Digital. Primary Care Mortality Database (PCMD) *2018 & 2019 St Helens figures are provisional*

Figure 4:All-age all-cause mortality trend 1999-2019 (36)

RATIONALE FOR CURRENT STUDY

Despite the current literature evidencing the clear benefits of DSME on behavioural choices, $HbA1_c$ levels and reduced risk of morbidity and premature mortality (38) attendance and completion levels remain poor. There is minimal understanding of the impact of non-completion of DSME programmes on $HbA1_c$ or psychometric outcomes. Positive endpoints for DSME studies are typically based on participants who complete the full programme (22) with $HbA1_c$ (39) used as a measure of effectiveness yet often studies fail to demonstrate significant or lasting results despite being statistically powered (38).

There is scarce literature examining the impact of attrition on DSME effectiveness. Although a small retrospective study in the USA using secondary data analysis of 105 patient records reported patients who attended 1 or 8 hours or more of DSME had a significant reduction in $HbA1_C$ when compared to those who received no education (22). Evidence is available looking at diabetes prevention programmes which suggests each session attended is linked to a reduction in body weight between 0.26-0.3% (24,40) suggesting a positive impact with any level of engagement.

Internationally the benchmark for recording a patient as completed DSME is attendance at ≥60% of a programme's content (23,41–43), a discord with the literature measuring effectiveness of landmark studies at 100% completion (25,39). A record of DSME attendance is given for patients who sign up and engage with >10% of materials (23,41,43).

There is no research available measuring the impact of non-completion on UK DSME programme effectiveness or internationally on the impact of differing completion rates on patient reported outcome measures (PROMs) despite the acceptance of completion (≥60%) at discord with legendary studies benchmarking completed at 100%. The aims of this study are to explore if patients who attend minimal aspects (10%) of DSME programmes gain clinically significant improvements in ability to self-care compared to those who do not attend, and if the nationally accepted 60 % completion rate is as effective as 100% completion.

THEORECTICAL FRAMEWORK

Philosophical assumptions (also referred to as epistemology) influence our views about how phenomena should be approached (44) assisting researchers in refining the types of evidence required, how it should be collected, and how it should be interpreted. This quantitative study will adopt an experimental hypothesis driven design whereby the variable or intervention is controlled, with the exception of a control group, to attempt to establish causal effect of an intervention, in this case DSME completion rates. Whilst the most powerful and highly regarded form of experimental study remains the randomised control trial (RCT), this study will test the feasibility of conducting a full RCT.

This study positions itself with critical realism, often thought to be a useful middle ground between the naive realism associated with quantitative research 'what you see is what you get' and the subjectivity given to interpretive sciences. (45). Quantitative critical theory approaches are growing, complementing the objectivity afforded to quantitative designs with a social lens which considers social determinants of health. Whilst with any scientific method in which hypothesis are formulated there are inherent limitations, among them the problem of induction which prevents researchers from generalising observations on a select sample to the wider population, a fatal flaw in the logic of scientific research as the implication is nothing can be certain. Philosopher Karl Popper in 1935 acknowledged that whilst induction is a flaw in scientific research, the focus should not be in attempting to prove theories but trying to disprove them (46). The harder a researcher tries to disprove the null hypothesis the more confidence a reader should have in it (45). The DIABETES-PRO study focus is not in discovering new health care interventions but merely to test current interventions with small samples and generalising through the logic of induction and sophisticated statistical tests to measure and compare the efficacy of differing DSME completion rates for people with type 2 diabetes by translating variables into numerical data, a method often thought to be reductionist by nature (47).

4.1 Null hypothesis

Differing DSME completion rates have no impact on a person's ability to self-care, diabetes distress or health related quality of life.

RESEARCH QUESTION

Using a quantitative approach this feasibility study aims to explore if patients who attend minimal aspects (10%) of DSME programmes gain clinically significant improvements in ability to self-care compared to those who do not attend, and if the nationally accepted 60 % completion rate is as effective as 100% completion on patient reported outcome measures.

5.1 Research question

1. What is the impact of differing completion rates of DSME programmes on ability to self-care (primary outcome), diabetes distress and health related quality of life in type 2 diabetes.

5.2 Outcome

The primary outcome measure will be measured as:

- Change in self-care activities outcome measure (pre and post intervention) using the Diabetes Self-Management Questionnaire - Revised (DSMQ-R) scale (48).

Secondary outcome data will capture data on:

- Change in diabetes distress (pre and post intervention) using the Problem Areas in Diabetes (PAID) tool (49).
- Quality of life outcome measures (pre and post intervention) using the PROMIS-Global Health V1.2 scale (50).

Other preliminary data will explore whether deprivation and diabetes duration have any impact on PROMs across the four groups.

STUDY DESIGN AND METHODS OF DATA COLLECTION

This is a quantitative feasibility study focusing on the impact of differing completion rates of DSME programmes on psychometric outcomes pre and 4 months post intervention.

6.1 Design

This is a single-centre randomised feasibility study evaluating the impact of different completion rates of DSME programmes on psychometric outcomes specifically looking at ability to self-care, diabetes distress and quality of life. DSME will be the intervention and will typically be delivered within 3 weeks of the baseline appointment. There is a deliberate short separation between education intervention and follow up psychometric tests of 3-4 months to allow participants the opportunity to adopt any behaviour changes following the DSME programme whilst minimising the risk of not receiving the full NICE recommended DSME programme and to broadly align with landmark studies. Landmark studies namely DCCT (26,27) and DESMOND (25) evidenced a statistically

significant improvement to PROMs at 4 months post education intervention, however $HbA1_c$ changes were not significant within this timeframe despite being statistically powered. A recent systematic review (38) concluded that as DSME is primarily focused on behavioural change to facilitate glycaemic control, efficacy measures should focus on behavioural and psychosocial changes, however these are often overlooked. This study is a feasibility trial and by its very nature is not statistically powered, therefore despite HbA1c being arguably the measure of choice within the literature for measuring effectiveness of diabetes interventions, this study will use PROMs as its primary outcome measure.

6.2 Study processes

Screening and recruitment

Potentially eligible participants meeting the inclusion criteria and not excluded by exclusion criteria (outlined in section 8.1) who are either due to attend the diabetes centre for new patient clinic, have been referred for DSME intervention or are on the monthly shared care report for newly diagnosed type 2 diabetes requiring an offer of DSME will be screened for entry into the study and added to a screening log sheet (appendix 1). Potentially eligible participants due to attend new patient clinic will be invited into the study by NP clinic letter (appendix 1) with attached participant information sheet (PIS) (appendix 1). Letters will be posted ahead of their clinical appointment. For potential eligible participants identified through DSME referrals or the monthly shared care record report will be sent a telephone screening letter (Appendix 1) and PIS prior to meeting with the researcher. Study recruitment technique is outlined in further detail in section 8.2.2.

At the screening meeting potentially eligible participants will be asked to confirm they have read the PIS and invited to ask questions about the research. Where patients decline to take part in the research, they will be reassured this will not have any impact on their current or future treatment. Participants who give written informed consent will be enrolled onto the study. The researcher will utilise an informed consent checklist (Appendix 1) to ensure consistency and that all elements for informed consent have been completed. Participants will be consented for informing their GP, this is made clear in the PIS.

Visit 1

At enrolment baseline characteristics will be recorded from the electronic medical record, or where not available directly from the patient: NHS number, age, sex, ethnicity, diabetes duration, postcode, latest HbA1c, prescribed glucose lowering agents, and a Charlson Comorbidity Index will be calculated. Postcode will be used to calculate indices of multiple deprivation (IMD) score.

Participants (n=120) will be randomised by permuted block strategy of 2:1 across four groups using an online randomisation software application designed for clinical trials (51,52). Due to the design of this study randomisation will not be blind to the researcher or participants. Group design will be as follows:

- Group 1: DSME 6 hours, 100% completed (completed).
- Group 2: DSME 3 hours 36 minutes, 60% completion (partial completion)

- Group 3: DSME 36 minutes, 10% of content (attended)
- Group 4: Delayed education (education not offered, not attended, or declined)

DSME programme overview is provided in appendix 1 giving a broad overview of DSME content by programme completion status. Local demographic data suggests that of the local population 46.4% are living in the most deprived neighbourhoods within the UK (9). Of the local population 19.3% have a reading age of 9-11 or below (53,54), are classed as being functionally illiterate and are therefore likely to struggle reading a paper questionnaire. Verbal support for completing the PROMs will be offered by the researcher to ensure participants from lower socioeconomic backgrounds are not excluded from participating in the DIABETES PRO study as they are evidenced to make up a larger proportion of people with diabetes (55–57). Support will be limited to reading the questions verbatim.

Participants will be asked to complete three psychometric tests measuring self-care activities, diabetes distress and quality of life using the following validated tools: Diabetes Self-Management Questionnaire-Revised (DSMQ-R)(48), Problem Areas in Diabetes (PAID) scale (49) and the Patient Reported Outcome Measures Information System (PROMIS) Global Health scale v1.2 (50) (appendix 1).

Participants in groups 1, 2 and 3 will be asked to book a DSME session with the researcher, typically this should be no longer than 3 weeks from study enrolment. Research group DSME programmes (intervention) will be run by the researcher separate to routine patient DSME to minimise disruption of participants leaving part way through on patients.

Participants randomised to group 4, delayed education will not be required to attend DSME as part of the DIABETES PRO study. Collected data will be collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools. A REDCAP data collection tool has been included in Appendix 1 for reference. REDCap is a secure, web-based software platform designed to support data capture for research studies, providing an intuitive interface for validated data capture; audit trails for tracking data manipulation and export procedures; automated export procedures for seamless data downloads to common statistical packages; and procedures for data integration and interoperability with external sources (58,59) (see section 3.6 for further details).

Visit 2

To ensure there is enough information about the intervention within this study particular consideration has been given to discussing areas the National Institute for Health Research (NIHR) report to be inadequately detailed in rejected health research proposals (60). See table 2.

Table 2: NIHR adapted final checklist for health research proposals. (60)

Organisation • What type of trust is involved?	Mersey and West Lancashire Teaching Hospitals NHS Trust, previously St Helens and Knowsley Teaching Hospitals NHS Trust

• How big is the organisation? • How many study sites?	and Southport and Ormskirk NHS Trust serves a population of over 600,000 delivering care across 5 hospital sites, intermediate care, primary care, and community-based services. The specialist diabetes centre is based at St Helens Hospital and will be the single study centre for this research.
Location • What type of area is it? • Population demographics	The borough of St Helens has a legacy of poor health linked with deprivation and the town's industrial past. St Helens is ranked as the 26th most deprived local authority in England, its relative position having deteriorated since 2015 with almost 25% of residents living in the 10% most deprived neighbourhoods in the country (34). St Helens has widespread health deprivation with a higher-than-average diabetes prevalence of 9.2% (14,935 individuals) (20), versus 7.3% in England (35).
Patient group • Who is receiving the intervention? • How many patients are being seen? • Characteristics of the patients?	Patients with type 2 diabetes referred to the Diabetes Centre, St Helens Hospital for specialist intervention and / or DSME and / or registered with a St Helens GP and opted into data sharing will be screened for entry. The Diabetes department works closely with primary care colleagues to offer specialist advice, education, and guidance to patients with diabetes who are assessed and then discharged for clinical management by their GP. Referrals for DSME are made directly from primary care into DSME education sessions. The shared care report highlights any patient with a local GP who has had a first use of a type 2 diabetes code within the last month and have opted into data sharing. The use of the three recruitment streams for this study allows for a sample which is representative of the local population and is not limited to only patients requiring specialist led care. The DIABETES PRO study will aim to recruit 120 participants which will be randomised across four groups containing 30 participants each. Patients ≥18 years of age from a variety of socioeconomic backgrounds. St Helens has a predominantly white British population (96.5%), and this is likely to represented in the sample (37).
Workforce and staffing • Staffing skill, grade and	The researcher is employed by the Diabetes Centre as a clinical research fellow and is a Fellow of the HEA with experience teaching

profession • Staff new or existing • Training needed to deploy the intervention?	adult learners within higher education settings. The researcher has a clinical background as a podiatrist and is currently registered with the HCPC. The researcher is the patient education lead within the department and is in the process of accrediting the DSME programme with QISMET.
Intervention • How is the intervention different from normal care? • What does it look like? • Is it clear when it starts and finishes?	Clinical intervention of participants will not be altered. Participants will receive the same DSME programme as routine clinical patients. Normal delivery of DSME programmes is by a diabetes specialist nurse or dietician. Research DSME programmes will be, where possible, delivered by the researcher for consistency. Participants will be reminded at the beginning of the DSME programme that this is a research study and that some participants will leave after 36 minutes, 3 hours and 36 minutes, with others remaining for the full 6 hours programme. Reminders will be given at the time points in which participants from groups 2 and 3 should leave.
Contextual information • Policy initiatives related to the intervention?	DSME is NICE recommended for all patients newly diagnosed with type 2 diabetes with annual refresher thereafter (15). The National Diabetes Audit suggests 71% of people with type 2 diabetes are offered DSME, with an average attendance rate of 7%. Local records suggest that of those that start DSME (9%) only 12.6% complete the programme (20).

Visit 3

Between 3-4 months post intervention participants will be asked to repeat baseline psychometric tests. For participants in group 4 this will be 4 months from enrolment. This will be the end of the study.

At the end of the study participants in groups 2, 3 and 4 will be offered a full DSME programme.

6.3 Data Collection

A REDCap data capture template has been created for collection and analysis and included in Appendix 1. REDCap which provides a secure platform for clinical research studies (58,59) will be utilised for data capture. Screening and baseline demographics will be obtained from the patient electronic record system, if any demographic information is unavailable this will be collected direct from the participant. Paper questionnaires will be completed by hand by study participants supported by the researcher and subsequently entered on the

data capture sheet by the researcher (example data capture template in appendix 1). To ensure consistency of the data being collected DIABETES-PRO pathway checklists will be used for visits 1, 2 and 3 (appendix 1).

6.4 Data Analysis

Descriptive analysis will be completed for all demographic data presenting continuous variables as means ± standard deviation and categorical variables as numbers (%). Data will be tested for normality using a Sharipo-Wilk test and subject to visual inspection of histograms and normal Q-Q plots.

Psychometric outcomes will include the Diabetes Self-Management Questionnaire-Revised (DSMQ-R)(48), Problem Areas in Diabetes (PAID) scale (49) and the Patient reported outcome measures information system (PROMIS) Global Health scale v1.2 (50). Data will be treated as continuous and analysis of the difference in the mean before and after intervention will be conducted using an analysis of variance (ANOVA) test to check for statistical and clinical difference in the mean across the four groups.

Statistical analysis will be conducted using IBM® SPSS® Premium 29 with support from University of Liverpool statisticians. The alpha level will be set at 5% for statistical significance.

Whilst a statistically significant difference is desirable, it is important to understand what would represent a meaningful clinical change for a patient. As such the minimal clinically important difference (MCID) will be reported to measure the smallest difference in which the patient would perceive a benefit (61–64). Where the MCID is not published this will be calculated using a distribution-based derivation using 0.5 SD of the observed change in PROM score (62,65). Whilst this approach is not without its limitations (61,63) no consensus on the ideal means of determining the MCID is available (63). A systematic review concluded that 0.5 SD of the observed change approximated the published MCID in the majority of cases popularising this derivation in the literature (65).

MCID will be classed as >2 T-score points for the PROMIS Global Health v1.2 (66) in which physical health and mental health are given separate T-scores with a 95% confidence interval. The MCID will be calculated for PAID and DSMQ-R.

Recruitment of participants and the number of dropouts will be reported descriptively (frequencies and percentages). Due to the aims of this study considering differing completion levels of DSME, intention to treat analysis will not be used. Where participants allocated to a group do not fully complete the required amount of DSME there results would be withdrawn from the final analysis.

6.5 Data Storage

All collected research data will be inputted by the researcher onto REDCap using a pseudo identifier and accessed via an NHS password protected encrypted computer. All physical copies of consent forms, pathway checklists and completed questionnaires will be documented and filed securely in a locked filing cabinet on NHS property within one day of collection. Study pathway visit checklists (Appendix 1) and consent forms will contain

identifiable patient information labels (NHS number, name and date of birth) , these will only be used by the researcher and will not be shared. Data will be given a unique study identifier at the point it is entered onto REDCap.

All participants will be given a unique study identifier which will be recorded on the screening and recruitment log (appendix 1). Patient identifier information will be kept in a separate, password protected database at the point of entry into the DIABETES-PRO study which will document a participants NHS number along with their unique study number.

All data will be stored until data analysis is completed at which point it will be archived in line with Mersey and West Lancashire Teaching Hospitals NHS Trust R&D standard operating procedures (67) . Physical copies of data will be accessed on site (Diabetes Centre, St Helens Hospital) and destroyed when no longer required.

STUDY SETTING

This is a single-centre study. All research activity including participant identification, recruitment, data collection and analysis will be conducted at the Diabetes Centre, St Helens Hospital, Marshalls Cross Road, WA9 3DA. A representative convenience sample will be used of patients who have been referred to the Diabetes centre for support, education and / or advice with their type 2 diabetes or are highlighted via a shared care report as being newly diagnosed with type 2 diabetes in the last month by their primary care provider.

Data will be stored at the Diabetes Centre until the point of data lock (completion of analysis) at which time it will be archived in line with Mersey and West Lancashire Teaching Hospitals NHS Trust R&D guidelines.

SAMPLE AND RECRUITMENT PARTICIPANT ENTRY

8.1 Eligibility Criteria

8.1.1 Inclusion Criteria

All patients with a diagnosis of type 2 diabetes aged ≥18 years of age referred to the Diabetes centre who are able to provide informed consent and are responsible for daily management of their diabetes will be screened for entry into the study.

8.1.2 Exclusion Criteria

The following patients will be excluded entry into the study:

- Lack capacity to make an informed decision.
- A diagnosis of type 1, type 3c, Maturity-onset diabetes of the young (MODY) or gestational diabetes.

- Received structured education for their diabetes within the last 12 months either online or face to face.
- Require 1:1 education support e.g., requires interpreter.
- Patients unable to attend for structured classroom education e.g., housebound.

8.2 Recruitment

8.2.1 Sample Size

A sample size of 24-50 participants per group is deemed adequate within a feasibility study to estimate effect sizes and inform future DSME modifications and research (68,69). A sample of 120 patients will be enrolled onto this study allowing for adequate numbers (n=30) across the four groups, controlling for expected participant drop out. Monthly recruitment targets are pre-specified in a study progression criteria table (table 3) to ensure an adequate sample size is achieved for data analysis.

The diabetes outpatient department receives a on average 24 referrals for DSME per month with a mean monthly attendance rate of 21 patients. Locally an average of 86 patients are newly diagnosed with type 2 diabetes each month (20), patients who have opted in for data sharing are contacted with an offer of DSME. This has been used to inform realistic recruitment rates. Recruitment rates will be kept under review and discussed with supervisors should the monthly figure fall below projected numbers.

Table 3:Progression criteria and study status

Criterion	Green	Amber	Red
Monthly recruitment	≥ 17 participants	14-16 participants	< 13 participants
Retention rate	>80% at endpoint	60-80% at endpoint	<60% at endpoint

~~8.2.2~~1.2.2 Sample identification and technique

A convenience sample of 120 participants will be recruited for this study through three existing streams with potentially eligible participants added to the screening log sheet (appendix 1) and the pre-visit 1 section of the DIABETES-PRO study visit 1 pathway will be completed (appendix 1).

1. Clinic lists of new patients due to attend the diabetes centre at St Helens Hospital are available on the hospital patient administration system. The hospital electronic record will be used to screen for potentially eligible participants from the clinical list by the researcher. Potentially eligible participants due to attend new patient clinic will be invited into the study by letter (appendix 1, NP clinic screening letter) with attached PIS which will be posted ahead of their clinical appointment. On the day of their clinical appointment the researcher will meet potentially eligible participants to check they received the PIS and to answer any questions. Where potentially eligible participants agree they will be invited for

screening. Following screening, where eligible participants agree to be involved in the research and provide written informed consent, they will be enrolled in the study.

2. Patients who have been referred by their GP for DSME are called and offered education. Education referrals will be used to screen for potentially eligible participants from those awaiting a DSME appointment by the researcher. Potentially eligible participants will be asked as part of the DSME booking process if they would like information on the research. Where potential eligible participants agree a letter (appendix 1, telephone screening letter) will be sent out with a PIS and a screening appointment will be made with the researcher. Screening appointments will be offered either at the Diabetes Centre or as a home visit. Following screening, where eligible participants agree to be involved in the research and provide written informed consent, they will be enrolled in the study.

3. Patients who have opted into data sharing and have been diagnosed with type 2 diabetes within the last month in primary care are reported via the shared care record, called and offered DSME. As part of this process potentially eligible participants will be screened and identified by the researcher Potentially eligible participants will be asked as part of the DSME booking process if they would like information on the research. Where potential eligible participants agree a letter (appendix 1, telephone screening letter) will be sent out with a PIS and a screening appointment will be made with the researcher. Screening appointments will be offered either at the Diabetes Centre or as a home visit. Following screening, where eligible participants agree to be involved in the research and provide written informed consent, they will be enrolled in the study.

The researcher is employed as a diabetes clinical research fellow in the Diabetes Centre at St Helens Hospital and therefore already a member of the patients existing clinical team, however, is not providing direct clinical care to any potential participants. Clinical appointment lists and patient records will be obtained by the researcher in her existing NHS role. Sampling will continue until the required number of participants are recruited.

A screening and recruitment log will be stored in the study file and will include the following information: patient initials, screening outcome date of consent, if consent was refused, did/did not meet inclusion/exclusion criteria, date entered the study, unique identifier, randomisation group, study status (ongoing, withdrawn, completed, died) (70,71). A blank copy of the screening and recruitment log is included in appendix 1. Mersey and West Lancashire Teaching Hospital NHS Trust R&D department will be informed of all participants recruited to the DIABETES-PRO study.

8.2.3 Informed Consent

The Participant Information Sheet (PIS) and Consent Form is the written information that explains the nature of the research, procedures involved and associated risks. Written informed consent will be obtained before any study specific procedures are undertaken. Informed consent is an ongoing process for all participants. In obtaining and documenting informed consent, the researcher will comply with the applicable regulatory requirement(s) and adhere to Good Clinical Practice and to the ethical principles that have their origin in the Declaration of Helsinki. The European Commission Guidelines state that, 'subjects must be allowed sufficient

time to decide whether or not they wish to participate'. All PIS and consent forms will be identified by the date and version number.

Where possible potentially eligible participants identified through new patient clinic lists will be sent a covering letter (NP clinic screening letter, appendix 1) and PIS ahead of their clinical appointment using an adapted template from the HRA website. On arrival to clinic the researcher will greet the patient and ensure they have read and fully understood the information, answering any questions.

For patients identified through GP education referrals or the shared care record database report for newly diagnosed type 2 diabetes, interested potentially eligible participants will be sent a letter (appendix 1, telephone screening letter) and a PIS ahead of the screening appointment with the researcher. At the appointment with the researcher, either at the Diabetes Centre, or as a home visit, any questions will be answered.

In those agreeing to take part in the research, written informed consent will be obtained and countersigned by the researcher. Two copies will be made: one for the participant and one for scanning onto the patient electronic record by the R&D department with the research records retaining the wet ink version. Consent forms (appendix 1) have been designed using a template from the HRA website.

Recruitment packs will be used which consists of exact copies of the PIS, Consent Form, and an Investigator Consent Process Checklist which will record the participants NHS number, name and date of birth. Recruitment packs will be delivered to the research scanning collection point at the Cancer Research Team Office, St Helens Hospital within 24 hours (or the next working day) for scanning/recording purposes (70,71). Occasionally, consent could be taken but the participant may not meet eligibility after screening procedures, this will be recorded in the study related screening and recruitment log.

ADVERSE EVENTS

9.1 Definitions

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject, including unfavourable and unintended signs, including abnormal laboratory results, symptoms or a disease associated with treatment.

Serious Adverse Event (SAE): any untoward and unexpected medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**

- **Is a congenital anomaly or birth defect**

A risk assessment has been carried out for this study. Risks are scored according to severity and likelihood giving an overall risk score (please see figure 5). Identified risks are detailed in table 4.

Peer review feedback highlighted the risk of the researcher knowingly or unknowingly biasing results by supporting participants to complete the PROM tools. This has been risk assessed in table 5. To ensure transparency, support from the researcher will be limited to reading the questions verbatim for each of the PROM tools. This will be done for every participant to standardise the approach.

9.2 Reporting procedures

All adverse events will be reported. Depending on the nature of the event the reporting procedures below will be followed. Any questions concerning adverse event reporting should be directed to the Chief Investigator in the first instance.

9.2.1 Non-serious Adverse Events (AEs)

Potential Adverse Events (AEs) are outlined in table 5.

All such events, whether expected or not, will be recorded on a Case Report Form (CRF) and in the patient's medical notes.

9.2.2 Serious Adverse Events (SAEs)

No serious adverse events are anticipated for this study. Upon identification of an SAE the researcher would complete a study specific SAE form which would be sent to the Chief Investigator within 24 hours.

Contact details for reporting SAEs

Fax: +44(0)151 529 5888, attention Prof. John Wilding

Please send SAE forms to: j.p.h.wilding@liverpool.ac.uk

Tel: +44(0)151 529 5899 (Mon to Fri 09.00 – 17.00)

All SAEs will be reported to the REC where in the opinion of the Chief Investigator, the event was:

- **'related'**, i.e. resulted from the administration of any of the research procedures; and
- **'unexpected'**, i.e. an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs will be submitted within 15 days of the Chief Investigator becoming aware of the event, using the HRA Non-CTIMP safety report to REC form. The Chief Investigator will also notify the Sponsor of all SAEs.

For NHS REC approved studies please refer to https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/ - (Scroll to Safety reporting for non-CTIMP studies)

Impact Score	Likelihood /probability				
	1 Rare	2 Unlikely	3 Possible	4 Likely	5 Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible (very low)	1	2	3	4	5

Likelihood – Descriptor and definition
Almost certain - More likely to occur than not, possibly daily (>50%)
Likely - Likely to occur (21-50%)
Possible - Reasonable chance of occurring, perhaps monthly (6-20%)
Unlikely - Unlikely to occur, may occur annually (1-5%)
Rare - Will only occur in exceptional circumstances, perhaps not for years (<1%)
Impact - Descriptor and definition
Catastrophic – Serious trust wide failure possibly resulting in patient deaths / Loss of registration status/ External enquiry/ Reputation of the organisation seriously damaged- National media / Actual disruption to service delivery/ Removal of Board
Major – Significant negative change in Trust performance / Significant deterioration in financial position/ Serious reputation concerns / Potential disruption to service delivery/Conditional changes to registration status/ may be trust wide or restricted to one service
Moderate – Moderate change in Trust performance/ financial standing affected/ reputational damage likely to cause on-going concern/potential change in registration status
Minor – Small or short term performance issue/ no effect of registration status/ no persistent media interest/ transient and or slight reputational concern/little financial impact.
Negligible (very low) – No impact on Trust performance/ No financial impact/ No patient harm/ little or no media interest/ No lasting reputational damage.

Figure 5: Risk assessment template and legend

Table 4: Potential participant adverse study events and controls.

Risk	Initial Risk Score	Key Controls	Sources of Assurance	Residual Risk Score	Additional Controls Required	Additional Assurance Required	Action Plan (with target completion dates)	Target Risk Score
Participants become distressed after completing patient reported outcome measures highlighting diabetes distress	3 x 1	The use of PROMs selected for use within this study are validated tools approved for use in clinical practice however it may be possible that a participant becomes distressed if a score is not anticipated e.g., diabetes distress highlighted. Where participants are highlighted as having high levels of distress then a letter will be sent to their GP with their permission highlighting further support may be needed. Participants will also be given contact details for St Helens Think Well-Being team.	Validated PROMs designed for use measuring diabetes distress, quality of life and self-care abilities which have been used and designed in collaboration with people with diabetes. Psychological support pathway already in place locally.	3 x 1	None needed	None needed	Progress as planned	3 x 1
As a result of delayed or incomplete DSME participants are unable to adequately manage their diabetes	4 x 2	There is a national NICE recommended target to offer all patients DSME within 12 months of diagnosis. This study will potentially delay DSME access by 4 months, less than the nationally recommended 12 months. All participants will be offered a full DSME programme at the end of the study. As a result of participating in this study participants are likely to gain access to DSME sessions quicker than those on the routine waiting list.	DSME offers and attendance are recorded locally and are reported nationally via the National Diabetes Audit. Database will be monitored weekly to ensure no unnecessary delay in offering DSME programmes following completion of the research.	3 x 1	None needed	None needed	Progress as planned	3 x 1
As a result of the DSME programme participants worry about the impact of diabetes on their long-term health	2 x 1	DSME sessions are taught by health care professionals with experience working with people with diabetes and will be able to offer any advice and reassurance as required. As part of the DSME programme all participants will receive a short booklet about managing their diabetes at the start of the programme.	Education sessions will be QISMET accredited and are designed to support behavioural changes with patients. Information about the seriousness of diabetes is delivered sensitively to by trained health care professionals with experience in teaching.	2 x 1	None needed	None required	Progress as planned	2 x 1
Participants are concerned about how their data will be used and if they will be identifiable	3 x 3	Participants will be reassured as part of the screening and recruitment process about how data is handled and that a pseudocode will be used at the point their data is entered onto the study database. Only the researcher will have access to the cross-identifier checklist. Participants will be reminded that they are free to withdraw from the study at any point at which no further data about them will be collected.	Participant information sheet, consent form and data management plan.	2 x 1	None needed	None needed	Progress as planned	2 x 1

Table 5: Potential researcher bias risk assessment and controls.

Risk	Initial risk score	Key controls	Residual risk score	Additional controls required	Additional assurance required	Action plan	Target risk score
Researcher knowingly or unknowingly influences participants understanding of questions in an effort to support completion of item.	2 x 2	Researcher support will be limited to reading tool questions verbatim.	1 x 2	None needed	None needed	Progress as planned	1 x 2

10. REGULATORY ISSUES

10.1 Ethical Approval

Before the start of the study, a favourable opinion will be sought from the UK Health Department's Research Ethics Service NHS REC for the study protocol, informed consent forms and other relevant documents e.g. patient letters, consent forms and PIS. Health Research Authority (HRA) approval will be obtained where required.

The study will be submitted for Confirmation of Capacity and Capability. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions. Prior to the recruitment of any participants the Chief Investigator or designee will ensure that appropriate approvals are in place.

The researcher will work with Mersey and West Lancashire Teaching Hospitals NHS Trust research and development team throughout the process to implement and confirm their support for the study as required.

10.2 Confidentiality

The Chief Investigator will preserve the confidentiality of participants taking part in the study and will abide by the Data Protection Act 2018 and the UK GDPR as amended from time to time and any successor legislation in the UK and any other directly applicable regulation relating to data protection and privacy.

As discussed in section 6.5 all collected research data will be kept on an NHS password-protected encrypted computer. All physical copies of consent forms and completed questionnaires will be documented and filed securely in a locked filing cabinet on NHS property within one day of collection. All participants will be given a unique study identifier, and patient identifier information will be kept in a separate, password protected database at the point of entry into the study. Where data do need to be transferred between the researcher and supervisory team this will be via secure NHS-encrypted email or with a secure NHS encrypted USB drive.

All data will be stored until data analysis is completed at which point it will be archived in line with Mersey and West Lancashire Teaching Hospitals NHS Trust R&D protocols (67). Physical copies of data will be accessed on site (Diabetes Centre, St Helens Hospital) and destroyed when no longer required.

10.3 Indemnity

The University of Liverpool holds Indemnity and insurance cover with Newline Insurance Company, which apply to this study.

10.4 Audits

The study may be subject to inspection and audit by the University of Liverpool under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Framework for Health and Social Care Research (v3.2 10th October 2017).

10.5 Document Control

Any amendments to the study will be with agreement with the Chief Investigator and the researcher's supervisory team. Amendments to the protocol or associated study documents will be the responsibility of the researcher with advice and support from the supervisory team who will collectively agree if amendments are substantial or non-substantial and require re-submission to the REC. All amendments will be tracked and filed in the following fashion: 'study title' – 'document name' – 'document version number' – 'document creation / update date'.

Document version numbers are displayed as 'Major.Minor.Revision'. The first version of a document would be '1.0.0' with revisions displayed as '1.0.1', minor adaptations as '1.1.0' and major changes as '2.0.0'. Once updated documents have been ratified, old copies of the documents will be archived, and the new copies will replace them in the master file. Document revisions will be recorded in a separate document.

11. END OF STUDY

End of study will be classified as the end of data analysis at which point an end of study declaration will be submitted. Once the end of study is declared no study activity, other than final analysis of the data (following 'lock' of the study database) and report writing, will be undertaken. End of study will be declared to the research ethics committee as per University of Liverpool standard operating procedures(72).

12. DISSEMINIATION POLICY

12.1 Dissemination policy

Upon completion of the study the study data will be analysed and tabulated with findings and discussions that form as part of the analysis forming part of the researcher's PhD thesis. Publications, posters, and abstracts are planned as part of this process within suitable journals and professional national and international conferences. Following completion and publication of the research the data will be owned by University of Liverpool and will be made

available via the research data repository upon completion of the PhD. Participants will be sent an end of study summary after the final study report has been completed.

13. ARCHIVING

The University of Liverpool Information Management Policy (73), Records Retention Guide (74)and Records Retention Schedule Version CSD 3.0 (75) have guided decisions on data retention and disposal for this project. Archiving practices will follow processes of the sponsor (University of Liverpool), whereby the study master file which includes findings and output data will be kept in an appropriate format and storage for at least 10 years. Personal addresses, postcodes and telephone numbers of all potential participants will be in a password secured database on an NHS desktop computer and on the secure NHS trust server. They will ensure compliance with the legal requirements of the GDPR and the Caldicott principles adopted by the NHS. Paper data collection forms will be kept in a secure locked location at the study site. Consent forms will be retained as essential documents, but items such as contact details will be deleted as soon as they are no longer required.

All metadata records for the qualitative data will be uploaded onto the University research data repository. All records will be anonymised and identified by study number only in order to maintain confidentiality. The PI will have access to this data.

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15. Appendices

Provided as separate documents at request of sponsorship team.

15.2 Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	V1.0.1	31.1.24	Gemma Lewis	• The criteria 'Dementia' has been removed and will now be encompassed in the exclusion criteria of those who are unable to make an informed decision, allowing those who are able to provide informed consent ability to participate. • A second exclusion criterion states "Severe or enduring mental health problem which prevent group education attendance." This has been removed and will be encompassed within the exclusion criteria amended 'Patients unable to attend for structured classroom education'. • The Archiving section has been completed and guidance text removed • The End of Study definition states the Trust SOP will be followed but this should be the Sponsor SOP. This has been updated.
2	V1.0.2	07.02.24	Gemma Lewis	Section 13, Archiving revised following sponsor feedback and encompass The University of Liverpool Information Management Policy, Records Retention Guide and Records Retention Schedule Version CSD 3.0. Table included to give greater clarity.
3	V1.0.3	19.2.24	Gemma Lewis	Section 13 Archiving updated as per sponsor requirements.
4	V1.1.0	27.03.24	Gemma Lewis	Section 6.4 Data Analysis updated following REC feedback. Information included clarifies how dropouts will be managed within analysis of data.

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.