Study Title: Spotlight Consultations: Efficacy and Cost-effectiveness for Use In Routine Care with People with Type 1, Type 2 Diabetes or Pre-Diabetes

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Sponsor:	Southern Health NHS Foundation Trust
Funder:	Dexcom Inc. offered no-cost CGM devices and supplies

There are no conflicts of interest in relation to this research

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, HRA, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. LAY SUMMARY

Existing therapeutic interventions to treat diabetes are well known, yet the majority of people with diabetes do not consistently achieve blood glucose targets (even individual therapy targets) for optimal health, despite the large range of treatment options available, though continuing advancement in medical devices shows promise for improving glycaemic control. Such outcomes have remained stubbornly poor for decades. A recent study showed that >75% of young people and adults with diabetes do not achieve the American Diabetes Association glycaemic targets, despite the increase in the use of novel therapies and technologies over the past decade. Patient behaviour, individually supported in routine clinical care, is an important missing component to improved outcomes, in a medical healthcare model not ideally suited to supporting successful diabetes management. Healthy, self-care behaviours are particularly important in the day-to-day management of diabetes. In terms of type 2 diabetes prevention, although studies have shown that lifestyle interventions reduce the risk of diabetes by ~50% [1], the success of randomised controlled trials have not been translated to general practice and this is mainly due to limited engagement by eligible participants [2].

Healthcare professional burnout is at an all-time high with over half of physicians and a third of nurses experiencing symptoms [3]. This burnout epidemic is both detrimental to healthcare professional well-being, to patient care and to healthcare systems. There is a pressing need to develop interventions that lead to long term improvements in the patient: professional interface in routine clinical outpatient appointments in primary and secondary care. This will improve healthcare professional experience, patient care and lead to improved glycaemic and quality of life outcomes for people with diabetes.

In this proposal, we intend to build on recent real-world evidence collection and assess the clinical and cost-effectiveness of the Spotlight Consultation tool. This adaptive, dynamic smart survey-based tool, completed on a smartphone, tablet or computer, aids in the identification of the main personal barriers to optimal self-care behaviours taking into account the person's current treatment regimen, motivation and available resources. These identified personal barriers are then mapped onto several psychosocial/therapeutic axes, namely treatment-related, social support-related, psychologically-related and education-related, in order to identify pathways for intervention and support. These suggested pathways are intended to clarify an individual's needs and ultimately facilitate a discussion with their health care team to develop a plan to address those needs more effectively. The Spotlight Consultations tool is designed for routine clinical practice.

2. SYNOPSIS

Study Title	**Spotlight Consultations: Efficacy and Cost-effectiveness for Use In Routine Care with People with Type 1, Type 2 Diabetes or Pre-Diabetes**
Sponsor	Southern Health NHS Foundation Trust
Funder	Dexcom Inc. offered no-cost CGM devices and supplies
Study Design	Randomised controlled trial

Study Participants	Adults with type 1 diabetes, type 2 diabetes or pre-diabetes		
Sample Size	(n=100) participants for the control group and (n=100) participants for the intervention group. Qualitative evaluation: (n=20) participants randomised to the intervention group will be interviewed prior to receiving the intervention. Healthcare professionals involved in Spotlight Consultations delivery will be interviewed at the end of the trial (x2 per site) Process evaluation Interviews will be held with a subgroup of participants (n=6), healthcare professionals (n=3) and clinical trialists (n=2).		
Planned Study Period	Total length of the project: 12 months Total duration of participation per participant: 1 week.		
Planned Recruitment period	1st February 2021 until 31st Dec 2021.		
	Objectives	Outcome Measures	Timepoint
Primary	To determine clinical and cost-effectiveness of the Spotlight Consultations tools via multi-centre RCT in routine primary or secondary care clinic appointments between healthcare professionals and adults with type 1 diabetes, type 2 diabetes or pre-diabetes.	Consultation duration time. Secondary: HbA1c, diabetes distress, treatment satisfaction, functional health status, depression and anxiety, weight, acceptability, usability, HCP burnout, cost-effectiveness and perceived impact for patients and healthcare professionals.	Twelve-months of routine clinic list outpatient appointments per arm, to take account of variability in routine care delivery across centres
Secondary	Functional health status, diabetes distress, depression, treatment satisfaction, impact on self-care behaviours, HCP burnout, HCP treatment satisfaction and burden, hypoglycaemia (time less than	Questionnaires will be administered every three months and include Diabetes Distress Scale, Diabetes Treatment Satisfaction Questionnaire, SF-12 psychosocial functioning measure, EQ5D-5L, WHO-5 well-being index, PHQ-9, self-care inventory and anxiety (GAD). In addition, Maslach Burnout Inventory for HCPs, uptake and study recruitment; intervention usability; attrition	Baseline 6months 12 months

	70mg/dL) and hyperglycaemia (time above 180 mg/dL).	rates; participant experience; reasons for declining, taking part and dropping out.	

3. ABBREVIATIONS

CI	Chief Investigator
DSS	Diabetes Distress Scale
eCRF	Electronic Case Report Form
GAD-7	Generalised Anxiety Disorder-7
GCP	Good Clinical Practice
GP	General Practitioner
HCP	Healthcare Professional
NHS	National Health Service
HRA	Health Research Authority
ICER	Incremental Cost-Effectiveness Ratio
ICF	Informed Consent Form
IDF	International Diabetes Federation
NICE	The National Institute for Health and Care Excellence
PHQ-9	Physical Health Questionnaire-9
PIL	Participant/ Patient Information Leaflet
QALYs	Quality Adjusted life Years
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure
SF-12	Social Functioning -12
TID	Type 1 Diabetes
T2D	Type 2 Diabetes

4. BACKGROUND AND RATIONALE

There is an urgent need to develop interventions that lead to sustained improvements in glycaemic and quality of life outcomes for people with diabetes and that support diabetes prevention. Therapeutic interventions to treat diabetes have been shown to be effective in clinical trials, yet >75% of people with diabetes consistently do not achieve blood glucose targets (even individual therapy targets) for optimal health, despite the large variety of drugs, including insulin, and medical devices available e.g. insulin pumps [4]. Such glycaemic outcomes have remained stubbornly poor for decades and is a significant risk factor for microvascular and macrovascular outcomes. Patient behaviour, individually supported in routine clinical care, is an important missing component to improved outcomes, in a medical healthcare model poorly suited to supporting successful diabetes management.
Spotlight Consultations identifies the main personal facilitators and barriers to self-management and maps appropriate care pathways to those needs, thus providing personalized medicine for each individual according to their current situation, delivered with healthcare professional support [5]. It is designed specifically for routine clinical practice to reduce the burden on healthcare professionals, directly facilitating national roll-out at low cost, with no increase in outpatient or telehealth visit time. It has the potential to reduce the public health burden of diabetes and associated long-term complications significantly. The model can also be adapted to other health conditions.

4.1. Management of Diabetes is Challenging and Costly

Diabetes is a major burden for people living with the condition, for public health and for healthcare systems across the UK and the world. People with diabetes are responsible for their own day-to-day care, with occasional support from healthcare teams. Sub-optimal diabetes control is widespread, with severe consequences both for the individual, their family, healthcare systems and broader public health in terms of health costs, days lost to work and lack of productivity with associated financial loss to economies. As such, it is important to recognize the different needs of each individual and support skills development so that individuals are empowered to undertake effective disease self-management. Data from the International Diabetes Federation (IDF) shows that 10% of global health expenditure is spent on diabetes (US $760 billion), predicted to rise to $825bn by 2030. Indirect costs from premature death, disability and other health complications due to diabetes are estimated to add an additional 35% to the annual global health expenditure associated with the condition [6]. The intangible costs, however are less visible but include worry, anxiety, discomfort, pain, loss of independence, concerns about managing the condition, fears for future complications and their potential impact on quality of life. These are also significant contributors to the cost of diabetes.

4.2. Psychosocial Correlates and Determinants of Glycaemic Control

Depression is commonly reported to be 2-3 times more prevalent in people with diabetes than the general population [7]. This figure perhaps overshadows the significant number of individuals who do not report symptoms of depression, but experience diabetes distress. These emotions can be described as: feeling overwhelmed and defeated by diabetes; feeling angry about diabetes, frustrated by the self-care regimen and/or having strong negative feelings about diabetes; feeling that diabetes is controlling their life; worrying about not taking care of diabetes well enough, yet unable, unmotivated or unwilling to change; avoiding diabetes-related tasks that give feedback about consequences of poor control; and/or feeling alone/isolated with diabetes. In type 2 diabetes, distress (but not depression) was related

with poor glycaemic control and change in distress (but not change in depressive symptoms) was associated with both short- and long-term change in glycaemic control [8]. Similar relationships were found in T1D: diabetes-specific emotional distress (measured by the DDS) was related to glycaemic control in a Norwegian study and was also linked to worsening diabetes management over time in adults with T1D [9].

4.3. Health Care Visits and Goal Setting

Routine patient care visits currently leave both patients and healthcare professionals feeling frustrated both in primary and specialist care settings. The lack of understanding of the psychosocial burden of diabetes and the evolving consequences results in a negative impact on clinical practice with consequential negative outcomes for patients and increasing frustration for healthcare professionals. At present, health care visits are designed to focus on biomedical outcomes of diabetes by using a didactic medical model. Complex and detailed algorithms are supplied by various guidelines for the management of blood glucose, lipids, blood pressure and long-term complications, but these relate only to medical management. Even goals which have been mutually agreed upon are often not followed up, leaving patients frustrated and healthcare professionals struggling to provide tailored support. Typically, physicians interrupt their patients 11 seconds after they start describing their problems; approximately half of patients' concerns are not discussed, and in half of health care visits, patients and physicians disagree on the central problem presented [10]. Disagreement about treatment goals, inconsistency among healthcare teams and confusion about treatment priorities are associated with poorer outcomes [5].

While health coaching has received much attention, results have been inconsistent. Cameron-Tucker et al [11] showed no significant difference between intervention and control group with the control group actually improving physical activity rather than the intervention group. Similarly, Walters et al [2013][12] reported no significant differences in health-related quality of life nor in hospital admissions. It could be that variation in definition or poorly applied theoretical underpinning contribute to such results.

4.4. A Paradigm Shift Centred on a Collaborative Approach is required

Despite the guidance, there remains a widespread lack of understanding of the impact of the psychosocial burden of diabetes and more specifically how to address it. Consistently poor outcomes highlight the urgent need for a paradigm shift to a more holistic, truly person-centered approach. Healthcare users, including people with diabetes, often lack awareness of their rights and responsibility to influence service provision and affect healthcare change in their own locality. Concurrently, there has been a failure by healthcare systems to create the necessary organizational and structural changes to provide optimal care. Health care visit remain, for the most part, firmly rooted in the medical model and medical advice continues to be commonly provided by 'expert' healthcare professionals in didactic clinic visits rather than through collaboration with patients providing an evaluation of individuals' personal needs and barriers. A paradigm shift away from a purely medical model to a greater emphasis on psychosocial aspects of diabetes has long been advocated but what this looks like in practice has remained opaque.

A collaborative care approach to diabetes management has long been a goal by which care is individualized, with the person with diabetes at the heart of decision-making, providing care that is

respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions. What person-centered care means on a practical perspective, however, remains unclear. Many of the components of collaborative care already exist and have been debated widely, yet there remains an urgent need for action to translate these into practical, enhanced care with people with diabetes in the driving seat, supported by healthcare professionals. By incorporating several data collection variables within Spotlight Consultations, which is a novel HCP-facing intervention designed by the investigators, we will help individuals understand their personal barriers to behaviour change. By providing such relevant information and a range of choices of available healthcare options and care pathways (within the context of medical, social and environmental aspects) directly to the patient, we are able to tailor healthcare systems to that individual in a collaborative, co-goal setting environment with healthcare professionals.

The responsibility of self-management lies firmly with the person with diabetes with the support of healthcare professionals. However, healthcare professionals are ill-equipped to offer support for factors that are not diabetes-specific but which still do affect diabetes management. Removing the need for healthcare professionals to be responsible for patient actions, but rather providing an improved interaction between healthcare professionals and patients by exploring informed, co-decision making opportunities and showing possible care pathways would enable enhanced patient and healthcare professional experience, patient empowerment, improved decision-making and personalization of healthcare via appropriate education, therapies, devices and support tailored to the individual to achieve improved biomedical, psychosocial and quality of life outcomes.

Diabetes regimens are complex, requiring multi-factorial risk reduction strategies beyond glycaemic control. These include ongoing self-management, education and support to maintain optimal diabetes control and prevent long-term complications. Interactions between individuals and healthcare professionals are enhanced by identifying the specific goals and questions important to an individual and providing choices of care pathways (via computer modelling algorithm) available to them. Thus, helping healthcare professionals provide tailored healthcare in a collaborative, joint goal-setting, co-decision making approach to maximise clinic visit time and get to the heart of what the individual needs help with. The specific benefits for this approach are that personal health systems are monitored (securely with strict confidentiality and unique user settings) using the Spotlight Consultations intervention, providing real-time, durable tailored, personalized healthcare by showing individualized specific care pathways to support enhanced diabetes self-management and successful outcomes including enhanced quality of life and psychosocial functioning, situating diabetes self-management more effectively in the context of each person's lifestyle and personal priorities.

Barriers to Self-Management: The barriers to optimal self-management of diabetes lie beyond A1c-defined glycaemic control. Novel, holistic, patient-centred, individualized care deliverable in routine clinic settings is required to help people with diabetes explore and better understand their barriers and facilitators, using intrinsic motivation to achieve better personal outcomes. This is in direct contrast to externally imposed targets that current exist. The proliferation of technologies for the treatment of diabetes is undeniable. However, as supported by our data, technology alone is insufficient to achieve optimal glycaemic and psychosocial outcomes and in fact, can sometimes contribute to greater feelings of despair and distress. Instead, a holistic, individualized and psychosocially empathic approach targeting quality of life outcomes, specifically diabetes distress is proposed.

The intervention, as applied as a practical tool will reframe the health care visit, providing key information about personalized risks, in the context of personal health systems that will target self-management behaviours. It comprises a brief personalized assessment used by the individual with

diabetes and completed by the healthcare professional with medical results, aligned to highly efficient and effective clinical care based on individuals' identified needs. This has direct patient benefit in that it is a personalized health system to increase individual awareness, empower the patients in greater management of their own health, improve metabolic control, personal awareness and self-efficacy, reduce acute and long-term complications and have a positive impact on quality of life and psychosocial functioning. Spotlight Consultations uses a range of quick and 'easy-to-answer' questions. This novel approach differs from traditional interventions by repositioning control of diabetes management to optimize patient empowerment, awareness and reduce personal uncertainties, exploring whole-life factors and improving interactions between individuals and HCPs.

4.5. Health Care Providers and Burnout

Burnout amongst healthcare professionals is a key challenge affecting healthcare practice, safety and quality of care. It is estimated that more than half of US physicians experience substantial symptoms of burnout, with burnout almost twice as prevalent among physicians as US workers in other fields. Nurses experience a similarly high prevalence of burnout and depression, with 43% reporting high degrees of emotional exhaustion. COVID has exacerbated this problem. Furthermore, there are significant correlations between a physician's sense of depersonalisation and patient satisfaction with their hospital care, and between a physician's job satisfaction and patient satisfaction with their healthcare and patient-reported adherence to medical advice. Healthcare professional burnout is independently associated with job dissatisfaction and increasing numbers of physicians plan to leave practice for reasons other than retirement or retire early. Costs to replace one physician depend on specialty, location, and length of vacancy, with estimated costs ranging from hundreds of thousands to more than $1 million. Research points to the possibility of physicians experiencing burnout or high workloads making more referrals and ordering more. Burnout may also increase health care expenditures indirectly via higher rates of medical errors and malpractice claims, absenteeism, and lower job productivity. The personal consequences however include 25% increased odds of alcohol abuse/dependence and 200% increased odds of suicidal ideation [13-16]. Spotlight Consultations aims to reduce the burden on healthcare professionals by removing the pressure to know all of the information required for best-practice decision-making when patients often are unwilling or unable to articulate the required information. Rather, priorities of the individual, alongside clinical outcomes are presented in a way that aids explanation to the patient of available care pathways.

The Spotlight Consultations pathway addresses current practice guidelines by helping each individual improve awareness and take greater control of their diabetes self-management, as well as identifying the top priorities for discussion with healthcare professional based on the answers provided through the online tool. The participant will be able to navigate their own personal responses forming the basis for discussion in the clinic visit. It is important to remember that these priorities may not be overtly diabetes-related, but will directly impact on an individual's self-efficacy, quality of life and ability to optimize diabetes self-management and should be addressed as such. Although diabetes is a complex, multi-factorial, progressive condition, the risk of complications can be reduced via treatment and optimal self-management behaviours.

4.6. Value to NHS:

- Reduced healthcare professional burnout
- Reduce consultation length per patient
- Enables clinics to target patients who DNA
- Reduce non-adherence to prescribed medication by improving understanding of need
- Spotlight Communications tools are based on an online platform and are accessible during pandemic situations when there is a move enmass to telemedicine.
- Spotlight Consultations are hybrid – can also be done face-to-face post COVID
- Improved patient outcomes leading to reduced long term complications
- Additional Tools in development for CVD, IBD, chronic pain, arthritis, cancers
- Scalable across NHS and other health systems. Can be licensed and sold at low cost per patient

5. STUDY DESIGN

Following recruitment and consent, each participant will complete baseline questionnaires. Participants will then be randomized into either the intervention arm or the control arm of the study at each centre for a period of 12-months (i.e. baseline and follow-up visits). Clinic visits will occur every 6 months i.e. baseline, six and twelve months within the intervention period. Haemoglobin A1c will be assessed, together with psychosocial outcomes throughout the trial, i.e. reflecting routine clinical care. The 12-month duration of intervention is determined by the goal to observe meaningful A1c changes AND reduced consultations times, alongside improvements on PROs; reduced burden / distress of HCPs and is sufficient for this purpose. We have considered alternative designs, such as a cluster randomised controlled trial, however it was decided that this approach would be more appropriate in order to minimize the number of participants needed for recruitment, and optimizes the total time and effort. Following the study, the participating centres may keep the tools and offer them to those in the control group.

6. AIMS AND OBJECTIVES RATIONALE

6.1. Hypothesis

Our hypothesis is that it is feasible and acceptable using the Spotlight Consultations tool, to improve outpatient visits, ensuring patient-driven healthcare to match the most relevant and appropriate care pathways to the personalized needs of the individual, thus optimizing outcomes and reducing burden on both the person with diabetes and the healthcare professionals.

6.2. Aims and objectives of the study

To determine clinical and cost-effectiveness of the Spotlight Consultations tools via multi-centre RCT in routine primary or secondary care clinic appointments between healthcare professionals and adults with type 1 diabetes, type 2 diabetes or pre-diabetes.

Methods/Study Design

Population: Adults with type 1 diabetes, type 2 diabetes or pre-diabetes

Intervention: Spotlight Consultations tools

Comparator: Usual Care

Outcomes: **Primary:** Consultation duration time. Secondary: HbA1c, diabetes distress, treatment satisfaction, functional health status, depression and anxiety, weight, acceptability, usability, HCP burnout, cost-effectiveness and perceived impact for patients and healthcare professionals.

Time: Twelve-months of routine clinic list outpatient appointments per arm, to take account of variability in routine care delivery across centres

7. PARTICIPANT IDENTIFICATION

7.1. Study Participants

As justified in the Statistical Analysis section below, we anticipate rolling enrolment of N=200 adults age 18+ years old. Each clinical site will recruit 30-35 participants for a total of 200. We will recruit participants with diabetes for at least six months and using any diabetes treatment, who are able to give informed consent without mental illness that would interfere with their ability to participate in the study (e.g. recent hospitalization for mental illness). Equal numbers of males and females will be recruited, and all racial/ethnic groups will be eligible for participation. Based on our experience in previous studies of this magnitude and duration, we expect that ~90% of recruited participants will complete the entire trial. We will aim to recruit a balance of broad pre-diabetes and diabetes therapy users across a range of HbA1c values.

Inclusion Criteria

- ≥18 years. There is no upper age limit
- Diagnosed with T1D or at risk of or diagnosed with T2D (including pre-diabetes) for at least 6 months
- Any diabetes treatment
- Willing/able to use Spotlight Consultations tool
- Ability to give informed consent
- Ability to speak and read English fluently

Exclusion Criteria

- <18 years
- Mental illness that could seriously reduce their ability to participate in the study
- Lack of capacity

8. PROTOCOL PROCEDURES

8.1. Recruitment

NIHR Local Clinical Research Network (LCRN) Wessex will be approached to facilitate recruitment to the study in NHS organisations. Identification of potential participants will also occur via GP or secondary clinic records searches. All patients with T1 or T2 diabetes registered at a participating site will be a potential participant. They will be contacted directly by their GP practice or secondary care clinic with information about the study and given time to decide whether they would like to participate and ask any questions. If they choose to participate, individuals will be enrolled to the study and asked to sign informed consent. We aim to approach 10 sites for participation into the study. Participants will be recruited online for virtual consultations or in person where appropriate and informed consent will be taken over the phone/video conference or online at the beginning of the questionnaire.

The exact way that a participant will be approached will be determined by that local site. For instance it may be via phone/video platform or face to face contact. If an eligible patient wants to take part in the study they will either complete the informed consent procedure process online or over the phone/video or in person for those who will be attending clinics.

8.2. Informed Consent

For participants who will be identified via Diabetes clinics in person, they will be provided with a participant information Sheet by the Diabetes Clinician and allowed enough time to read and decide to take part (approximately 24hrs). This will give them the opportunity to ask the Study investigators questions or other independent parties like PALS to decide whether they will participate in the study. If they decide to take part they will be asked to complete informed consent. They must personally sign and date the REC approved version of the Informed Consent form before any study specific procedures are performed. The informed consent procedure may take place through a paper copy of the consent form, or through verbal consent taken over the phone/video consultation or via online electronic consent process.

Participant Information Sheets and Informed Consent will be presented to the participants prior to taking part in the study, detailing clearly the exact nature of the Spotlight consultations study; what activities the participants will engage in should they decide to take part. It will be reiterated throughout the study that participation is voluntary and participants are free to withdraw from the study at any time for any reason without this impacting the care they are receiving from the clinical services.

In order to minimise social contact in light of the Covid-19 pandemic and varied local restrictions across the country, the option for informed consent to be taken over the phone/video or online platform will be utilised.

8.3. Randomisation

Once the consent process has been completed study participants will be randomized into either the intervention group or control group for 12 months. We will randomise on a 1:1 basis using computerised randomisation software.

Those randomised to the intervention group will be asked to complete study questionnaires and the Spotlight Consultation tool (approx. 3-5 minutes). The results of the Spotlight Consultation digital health tool will be discussed between the participant and healthcare professional during the outpatient visit along with identified matched care pathways and agreement made on best-fit action plan.

8.4. Recruitment and Retention plan

A multi-centre parallel group, individually randomized controlled trial, with pre-planned futility analyses to ensure the trial does not proceed if recruitment is inadequate. We have considered potential threats to delivery of the trial, including centres not being able to recruit sufficient patients or not being able to deliver the intervention. Throughout the trial period we will review progress against a number of criteria at three time points, namely end of months 1, 3 and 5, and assess this as red, amber or green each time.

Grade	**Meaning**	**Action**
Green	recruitment to target on time	Continue trial, keeping an eye on accrual
Amber	Recruitment progressing but more slowly than anticipated	Working with governance committees, seek root cause for under performance. Consider whether these can be mitigated through work with organizations or individuals within the study
Red	Recruitment not progressing within reasonable time period	Review the study with governance committees, taking steps as detailed under amber, but also explicitly considering recommending study closure

8.5. Interventions

To ensure effective and appropriate support for users of the Spotlight Consultation intervention, a manual of care will be given to HCPs with a matrix of care options, akin to a 'toolbox' approach addressing specific needs and providing a gateway to safe, reliable sources of support for patients. This manual will improve care choices through signposting of available therapies, devices and education,

referral pathways for additional education or psychological support and local resources e.g. support networks, peer support or online resources to fill gaps in service provision. Training for HCPs will be offered through this manual and will include background of underpinning theory, evidence-base and trajectory to improved outcomes. All tools have demonstrated mechanism of action which link to health outcomes.

8.5.1. Outpatient Screening Evaluation and Enrolment

All participants will provide informed consent. Study personnel will obtain routine vital signs and arrange for bloods for screening labs, including baseline A1c. A participant who meets all inclusion and exclusion criteria and is willing to be in a 12-month study, will be enrolled.

8.5.2. Patient-Reported Outcomes

All participants will also be asked to complete the validated: Diabetes Distress Scale (DDS) Diabetes Treatment Satisfaction Questionnaire (DTSQ), Depression (PHQ9), functional health status (SF-12), Well-being (WHO-5), Self-care Inventory (SCI) and functional health status (EQ5D-5L) on arrival or in advance of the virtual consultation and prior to completion of the Spotlight Consultation intervention. In addition, bespoke open-ended questions regarding expectations and experience. HCPs (two per site, thus twenty in total) will complete the validated Maslach Burnout Inventory at baseline, 6 and 12- month follow-up. All participant PRO scales have well-documented reliability and validity and will be used to assess patient-reported outcomes. These questionnaires will be repeated every three months and qualitative methods, e.g. one-to-one interviews exploring factors, facilitators, and barriers will be held at baseline and 12-months' follow-up. Questionnaires will be completed using Southern Health's survey service, Qualtrics XM online platform, which provides hosting of research questionnaires that study participants can complete online at their convenience and in the privacy of their home ensuring minimum clinical team influence.

8.5.3. Qualitative interviews:

A subgroup of 20 participants from the intervention arm will be interviewed via phone or online teleconference facility at baseline and the end of their participation. A purposive sampling approach will be taken to ensure representation across study participants in terms of ethnicity, gender, type and duration of diabetes, age.

Telemedicine or In Clinic Visits: Participants will have a telemedicine or in-person clinic visit as per their usual routine care during the trial. Study participants will complete a personal assessment on study iPad devices if face-to-face visit (for ease of visibility i.e. font size can be immediately increased easily for each individual user by 'swiping' to size required) or on personal smartphone or computer device if telehealth to identify their key diabetes priorities, assessing motivation, health beliefs, social support, resources, current therapy, self-care behaviours and needs. The support of a research assistant will be available if required. These priorities will be immediately available, calculated via an algorithm that scores responses to each question. Participants will view their data, which will be encrypted and secure, to consider their personal results prior to discussing with their HCP. This facilitates a joint goal-oriented clinic visit to meet individual needs of each patient. Other aspects of care are measured alongside these, including the individual's current therapy regimen, device options, diabetes education provision and needs and latest HbA1c result. Using an algorithm, a pictorial representation of current needs is calculated, along with the identification of potential discussion topics, priorities for behaviour change or

therapy modification. This brief summary provides an easy-to-read, visual snapshot. For the study, this assessment can be completed in the waiting room at clinics or at home via telehealth, however, in future it could be completed on any mobile smartphone/tablet device, with the results available for personal self-awareness, action and discussion with healthcare professionals. Screenshots and print-outs can be saved securely/provided to reinforce decision criteria and accompany agreed goals and targets for the individual to act upon, with copies placed on file at clinics for review at the next clinic visit.

HCPs will also see the results and care pathway options, identifying ways to meet the individual needs of each participant e.g. of pathways include referral to structured education, changes to medication, or signposting to online education and behaviour modification resources. HCPs and participants will discuss the priorities and possible options collaboratively in a co-decision making, person-centred approach. Clinic visit duration should not be extended as a result of this intervention (as demonstrated in previous research). Participants will be invited for repeat assessment as per routine care.

Usual Care All participants in the control group will continue to receive usual care. The only difference between the intervention arm and the control arm will be the use of the Spotlight Consultations intervention. Apart from this, all participants will continue to receive usual care as normal.

Spotlight Consultations Hosting: The Spotlight Consultations intervention is hosted on a responsive website and web application that scales to the platform that it is being accessed on, e.g. from Desktop to Laptop, Tablet or Smartphone. The intervention has been built using HTML5 and CS3, on a PHP framework and utilizes a user-friendly Content Management System (CMS) that will facilitate quick and easy maintenance and is open for use by multiple project administrators. The application clearly visualises the Tool's unique elements, interactive elements, with each representing the interaction required so that users receive a truly personal experience for their individual treatment needs. Spotlight Consultations is multi-lingual-ready and accessible via audio control as well as using the traditional navigation methods associated with a website and web application. This consistency of navigation tools provides intuitive control that are a key feature of the Tool's usability. It also ensures broad access to a wide population irrespective of health literacy, educational status or disease state.

Psychosocial Questionnaires

We will assess a series of psycho-behavioural characteristics through a set of validated questionnaires for participants **(Table 1)**. These questionnaires will aim at understanding how specific constructs are predictive of the integration of the Spotlight Consultation intervention in the patient's care and its efficacy at improving HbA1c and reducing glucose variability. Table 1 lists these measures, the relevant construct assessed, hypotheses, and internal reliability data. The instruments listed in Table 1 have established psychometric properties with well-documented correlations with adherence, glycaemic outcome, physical activity, and psychosocial functioning: and are widely used in diabetes research with adults.

Table 1 Psychosocial Questionnaires

CONSTRUCT	MEASURE	HYPOTHESES
Diabetes Distress	DDS[19]	Spotlight will ↓ distress
Depression	PHQ-9[20]	Spotlight may ↓ depressive symptoms
Anxiety	GAD-7[21]	Spotlight may ↓ anxiety symptoms
Social Functioning (for health econ.)	SF-12[22]	Spotlight will ↑social functioning vs usual care
Engagement	Self-Care Inventory (SCI)[23]	Spotlight will ↑ adherence vs. usual care
Treatment Satisfaction/Utility	Diabetes Treatment Satisfaction Questionnaire[24]	Spotlight will ↑satisfaction vs. usual care
Health Resource Utility	EQ5D [25]	Spotlight will ↓ health resource use
Well-being	WHO-5[26]	Spotlight will ↑ well-being
HCP Burnout	Maslach Burnout Inventory[27]	Spotlight will ↓ HCP burnout

8.6. Early Discontinuation/Withdrawal of Participants

If a participant who has given informed consent decides during the course of the study to discontinue or withdraw their participation before the study period ends, they will be withdrawn from the study. Identifiable data already collected with consent would be retained and used in the study. No further data would be collected or any other research procedures carried out in relation to the participant. The reason for withdrawal will be recorded in the CRF.

8.7. Definition of End of Study

The end of the study is defined as the completion of the last assessment measure with the last participant.

9. STATISTICS AND ANALYSIS

9.1. Health Economic Analysis

Within-trial analysis will be used to estimate the cost-effectiveness of the intervention compared with usual care. The analysis will follow a NICE 'reference case', with costs estimated from a healthcare perspective and outcomes quantified using Quality Adjusted life Years (QALYs).

Methods of analysis for the economic trial data will be pre-defined alongside the statistical analysis plan. QALYs will be estimated from EQ-5D and mortality data, using the area-under-the-curve method. Similarly, costs will be estimated at the patient level. Mean between-group differences in QALYs and costs will be estimated using a regression-based approach, including adjustment for baseline co-variates and interaction terms for pre-defined sub-groups, and allowing for clustering at hospital and/or practitioner level. Missing data will be imputed using an appropriate method, such as multiple imputation, in line with the statistical analysis plan. Results will be presented as an Incremental Cost-Effectiveness Ratio (ICER) if appropriate. Non-parametric bootstrapping will be used to estimate confidence intervals around estimated cost differences and ICERs.

9.2. Primary and Secondary Analysis Plan

Exploratory data analyses and graphical representations of the data will be used to check validity. The study design includes repeated measures on all outcomes; thus, we will use a linear mixed-effect model that corresponds well to this structure (e.g. Linear Mixed Models in SPSS), with "Participant" as a random factor and "Group" as a fixed factor. The models will adjust for age and duration of diabetes as fixed effects. We should note that similar results may be generated by repeated measures ANOVA, but mixed models handle missing data better (e.g. ANOVA only uses listwise deletion, which could reduce power and introduce bias towards study completers). A mixed model is also

more flexible and will allow us to address additional questions, such as introducing time between sessions as a continuous variable.

Specific Aims

SA1: **Consultation Time**: we hypothesize that Spotlight Consultations digital health tools will reduce consultation times, making them more focused and effective.

SA2: Clinical Effects of Spotlight Consultations: we hypothesize that Spotlight will improve key parameters of glucose control–haemoglobin A1c. Specifically: (i) A1c will be lowered (**primary outcome**), particularly for those with sub-optimal glycaemic control at baseline (A1c>7.5%); (ii) time in target range measured by CGM will concomitantly increase and (iii) diabetes distress will be reduced (key secondary outcome in SA2).

SA3: Psychosocial Effects of Spotlight Consultations: measured by a bank of patient-reported outcome measures. Psychosocial functioning is associated with patterns of poor lifestyle-related health behaviours, suboptimal glycaemic control, high glucose variability, and elevated risks for hypo- and hyperglycaemia. Individual expectations and experience, as well as factors driving treatment choice, determine further the degree of distress. Improving communication and encouraging intrinsic decision-making in goal-focused collaborative clinic visits with HCP will reduce distress and improve psychological health outcomes.

SA3: Relative Effectiveness of Spotlight Consultations: Assessment of Fidelity: Spotlight will offer personalized support to increase therapy acceptance, reduce therapy associated anxiety. Providing a clear understanding of pre-diabetes and diabetes-related priorities and preferred choice of care pathways of participants will reduce the burden on HCPs and decrease misunderstanding, mistrust or conflict in clinic visits. **Intervention Fidelity** will be compared to usual care to assess whether it leads to the same or different health benefits and psychological outcomes mixed-methods to determine acceptability, usability and experience of participation and impact on diabetes management and psychosocial functioning.

SA4: **Cost-effectiveness**: health economics analyses will assess cost-effectiveness of the intervention in routine care.

9.3. Qualitative Evaluation

The aims of the qualitative evaluation are to understand and explore:

- Participants' experiences, including gender specific experiences, of receiving Spotlight Consultations tool and health professionals' views about delivering it.
- The perceived benefits of Spotlight Consultations from participants' and health professionals' perspectives; and, their recommendations for future refinements.
- Any changes participants make to their diabetes self-management practices and treatment goals after receiving Spotlight Consultations intervention and why.

- Whether, in what ways and, why, Spotlight Consultations is delivered and received differently in different settings

- Whether there are any site-specific differences in how participants self-manage their diabetes after receiving Spotlight Consultations, and why.

9.3.1. ***Participant interviews***

20 participants randomized to receive the intervention will be interviewed prior to receiving the intervention to explore expectations, reasons for participation and perceived facilitators and barriers to achieving treatment goals. The **same participants** will be re-interviewed 6 months later to look at whether, how and, why, their diabetes self-management practices and treatment goals have changed in the intervening 6 months; and, any perceived barriers to achieving future changes and goals. These interviews will explore their experiences of receiving Spotlight Consultations tool; any changes made to their diabetes self-management practices, and why; short- and long-term treatment goals and the reasons for these; and perceived barriers and facilitators to achieving these goals. These interviews will also include detailed exploration of participants' historical diabetes management practices; previous contact with health professionals and diabetes management programs; and, their everyday work and family lives. The interviews will also explore participants' information and support needs and whether, and in what ways, the intervention and follow-up care could be changed or improved.

9.3.2. ***Health professional interviews***

Health professionals involved in Spotlight Consultations delivery will be interviewed once at the end of the trial. Interviews will explore: previous experiences of delivering self-management interventions for adults with diabetes; perceived benefits of Spotlight Consultations as compared to other interventions; experiences of, and views about, the training received to deliver Spotlight Consultations; barriers and facilitators to intervention delivery; perceived impact of Spotlight Consultations on participants' diabetes self-management practices; and, how Spotlight Consultations could be changed/improved for future use.

Qual Topic guides: Participant and health professional interviews will be informed by topic guides, with questioning kept sufficiently flexible to enable individual issues to be identified and explored. All interviews will be audio-recorded, transcribed in full, and early interviews will be reviewed by the research team to determine whether any alterations to the topic guides need to be made.

9.3.3. ***Process Evaluation***

The process evaluation will be undertaken 'to explain discrepancies between expected and observed outcomes, to understand how context influences outcomes, and to provide insights to aid implementation'. Interviews will be held with a subgroup of participants (n=6), healthcare professionals (n=3) and clinical triallists (n=2).

9.4. Sample Size Determination

The number needed for a two-sample t test with standardised effect size of 0.50 at alpha=0.05, 90% power is 86 per group [17]. Thus, we will recruit a minimum of 100 participants for the control group and 100 participants for the intervention groups to allow for potential dropout. Previous feasibility data from real-world evidence collection has demonstrated feasibility, acceptability and improved consultations across three centres in the UK and USA.

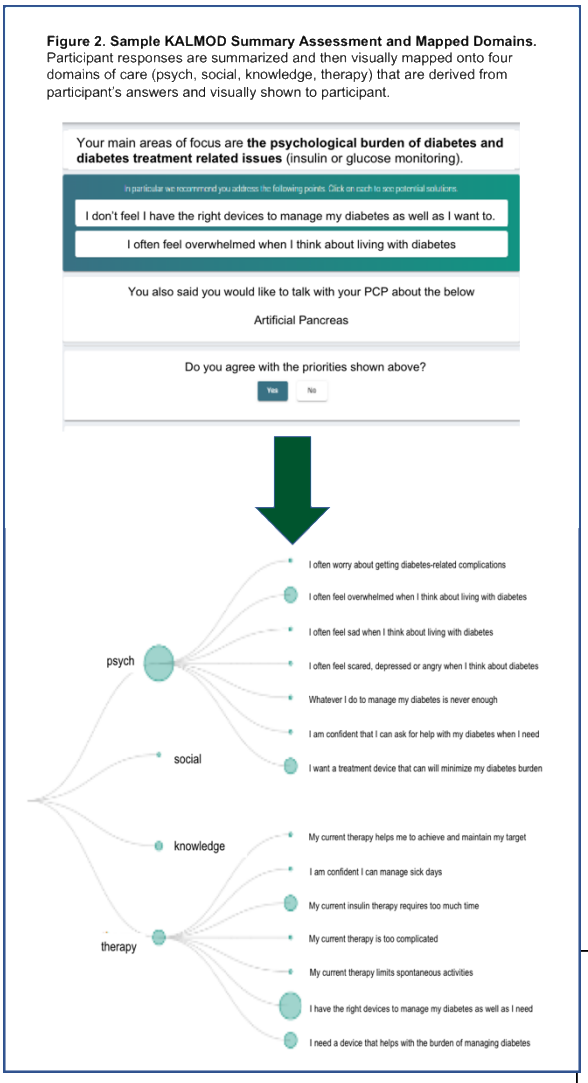

Figure 2. Sample KALMOD Summary Assessment and Mapped Domains. Participant responses are summarized and then visually mapped onto four domains of care (psych, social, knowledge, therapy) that are derived from participant's answers and visually shown to participant.

Patients complete a very brief digital health assessment on a smartphone, tablet or computer prior to their routine appointment. Based on their responses to the questions, which are weighted throughout to identify key priority concerns, they are guided through tailored and specific questions relevant to them. The HCP and patient can each click on the priority concern and they are presented with appropriate care pathway choices for discussion. This quick and easy tool provides much more effective outcomes, without increasingly office visit times, rather it immediately makes visits more relevant and productive. Priority concerns and care pathways are mapped in real-time to four domains of care, namely: i) therapy-relevant, ii) psychological burden, iii) social support or iv). diabetes knowledge-related. Results are presented clearly, using graphics to help visualise the process (Figures 2 and 3 which represent results for individual with diagnosed T1D, however separate tools exist for obesity/pre-diabetes and T2D). This unique intervention improves communication and understanding between patients and healthcare professionals, identifying appropriate care pathways for discussion and action.

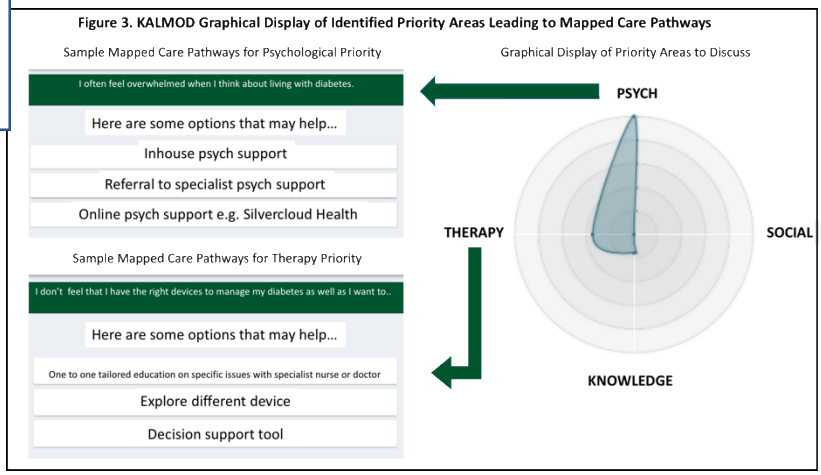

Figure 3. KALMOD Graphical Display of Identified Priority Areas Leading to Mapped Care Pathways

Pilot study data shows that Spotlight Consultations (formerly KALMOD working title) is acceptable, relevant and tailored to the individual needs of adults with diabetes.

9.4.1. ***Preliminary Data:***

Data from pilot studies show that Spotlight Consultations is acceptable, relevant, and tailored to individual needs, and that it can be implemented in clinical practices. We have undertaken an iterative process thus far to ensure Spotlight Consultations is relevant, acceptable and easy-to-use. A co-design approach was taken alongside qualitative research. This extensive phase focused on diabetes and whether the tool met the needs of users in terms of acceptability, usability, and relevance to their own specific needs and priorities. After this, minor modifications were made to wording of

questions and a refinement of weightings was applied. The next phase was conducted in December 2018 and January 2019 with patients and healthcare professionals in the UK and US. These analyses again focused on acceptability for patients, but also included an assessment of clinical relevance, utility, acceptability and relevance within routine clinical care for health care professionals.

In the first phase analyses, three focus groups (n = 12) and six interviews were conducted with participants completing the tool and providing feedback, with a further 13 participants completing the tool and providing feedback through an online survey. Key positive themes were ease of use, relevance, personalized feedback, and simplicity of the tool, for example, "I love this, quick simple and effective." The tool was revised in line with recommendations regarding wording of some questions to aid clarity and remove ambiguity. Survey data showed that all participants believed the tool was intuitive and simple to use, relevant, and easy to understand. Sixty-nine percent (n = 9) thought it would improve their clinic visits with their health care team and 61% (n = 8) felt it would help the health care team better understand their needs.

The second phase involved one-to-one interviews with 12 patients (7 female, 5 male aged 18–74 years) and 8 health care professionals (4 diabetologists, 2 diabetes specialist nurses, and 2 allied health professionals). All participants expressed enthusiasm for the tool and reported that it accurately identified personal priorities and clear appropriate care pathways to meet those needs. All health care professionals stated that it would be useful in clinic to potentially reduce clinic visit times and improve communication, as well as aiding greater understanding of patient needs. Minor further revisions were recommended to question structure [18].

A real-world feasibility study recently confirmed that Spotlight Consultations is 100% acceptable and 100% feasible in routine care, improving consultations without extending consultation times. Data is submitted to the ATTD 2021 conference and under medical journal peer review currently, but in summary n=49 adults took part (*n*=31T1D, *n*=18 female; n=18T2D *n*=10 male). Each used Spotlight Consultations tools which identified two priority concerns per participant. 'Psychological burden' was most common (T1D *n*=27, 87.1%) followed by 'gaining more skills' (T1D *n*=19, 61.3%), 'improving support' (*n*=8,25.8%) and 'diabetes-related treatment issues' (*n*=8, 25.8%). Similarly, psychological burden was the primary concern for participants with T2D (*n*=18,100%) followed by 'gaining more skills' (n=7,38.9%), 'improving support' (*n*=7,38.9%) and 'diabetes-related treatment issues' (*n*=4;22.2%). Appropriate care pathways were satisfactorily agreed with each participant. Participating healthcare professionals reported high levels of satisfaction with the tools. Spotlight is acceptable and feasible for use in routine care.

10. DATA MANAGEMENT

A Data Management Plan (DMP) providing full details of the study specific data management strategy for the trial will be available and a Trial Schedule with planned and actual milestones, CRF tracking and central monitoring for active trial management created.

Data queries will either be automatically generated within the eCRF, or manually raised by the study team, if required. All alterations made to the eCRF will be visible via an audit trail which provides the identity of the person who made the change, plus the date and time.

At the end of the study after all queries have been resolved and the database frozen, the PI will confirm the data integrity by electronically signing all the eCRFs. The eCRFs will be archived according to Southern Health policy and a PDF copy including all clinical and Meta data returned to the PI for each participant.

10.1. Data custodian and data ownership

Name of data custodian: Dr Peter Phiri

Name of data owner: Southern Health NHS Foundation Trust

10.2. Data Security

All data will be collected and stored in a secure password protected computers. Access to systems is severely restricted to specific research staff. Only members of the research team will know the passwords and will therefore be able to access the electronic data.

11. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures. All researchers involved in the study will have up to date GCP training.

11.1. Data Monitoring

Participant data will be entered remotely at site and retained in accordance with current Data Protection Regulations. The PI is responsible for ensuring the accuracy, completeness, and timeliness of the data entered.

The participant data is pseudo anonymised by assigning each participant a participant identifier code which is used to identify the participant during the study and for any participant- specific clarification between Southern Health and site. The site retains a participant identification code list which is available to site staff.

The Informed Consent Form will specify the participant data to be collected and how it will be managed or might be shared; including handling of all Patient Identifiable Data (PID) and sensitive PID adhering to relevant data protection law.

Trained personnel with specific roles assigned will be granted access to the electronic case report forms (eCRF). eCRF completion guidelines will be provided to the investigator sites to aid data entry of participant information.

Only the Investigator and personnel authorised by them should enter or change data in the eCRFs. When requested, laboratory data must be transcribed, with all investigator observations entered into the eCRF. The original laboratory reports must be retained by the Investigator for future reference.

12. SAFETY

Participants will be provided with details of support resources to refer to should they be at all concerned about their participation in the trial or the information they discover about their approach to diabetes management.

12.1. Potential Risks:

The risks associated in taking part are very small. Taking part may make participants think more about their own mood and how they feel about their diabetes, their approach to self-management and views on diabetes burden and its impact more broadly.

The study team will make every effort to avoid compromising a participant's confidentially that may result in serious negative social, legal, or economic ramifications for the participant. The team will adhere to Ethics regulations during this study.

13.1.2. Adverse Event (AE)

Any untoward medical occurrence in a participant or clinical study participant which does not necessarily have a causal relationship with study treatment or participation. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the study treatment or participation (regardless of causality assessments).

13.1.3. Serious Adverse Event (SAE)

SAE is any untoward medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the participant 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 hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**
- Other important medical events***.

*'life-threatening' in the definition of 'serious' refers to an event in which the patient 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.

**Hospitalisation is defined as an inpatient admission, regardless of length of stay, even if the hospitalisation is a precautionary measure for continued observation. Hospitalisations for a pre-existing condition, including elective procedures that have not worsened, do not constitute an SAE.

***Other important medical events may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

Note: It is the responsibility of the PI or delegate to grade an event as 'not serious' (AE) or 'serious' (SAE).

13.2. Seriousness

A complete assessment of the seriousness must always be assessed by a medically qualified doctor who is registered on the delegation of responsibility log; this is usually the investigator. All adverse events that fulfil the criteria definition of 'serious' must be reported to Southern Health using the Serious Adverse Event Report Form – Non-CTIMP. Specific exceptions to this (as listed below) should be recorded as AEs rather than SAEs. All SAEs must be reported immediately by the PI at the participating centre to Southern Health

Exceptions**:**

For the purposes of this study, the following SAEs **do not** require reporting to Southern Health using the Serious Adverse Event Report Form – Non-CTIMP:

- Hospitalisations for elective treatment of a pre-existing condition

13.3. Causality

A complete assessment of the causality must always be assessed by a medically qualified doctor who is registered on the delegation of responsibility log; this is usually the investigator. If any doubt about the causality exists the local investigator should inform Southern Health who will notify the Chief Investigator. Other clinicians may be asked for advice in these cases.

Relationship	Description	Event Status
Unrelated	There is no evidence of any causal relationship	Not related to treatment
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not	Not related to treatment

	occur within a reasonable time after administration of the study treatment). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).	
Possibly	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the study treatment). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).	Related and expected SAE/ Related and unexpected SAE
Probably	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.	Related and expected SAE/ Related and unexpected SAE
Definitely	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.	Related and expected SAE/ Related and unexpected SAE

In terms of event status; **Not related to treatment** would highlight that the SAE is not related to the trial treatment. **Related and expected** SAE would signify that the SAE is related to the trial treatment and is expected (according to the list of expected events listed in the protocol). **Related and unexpected SAE** would be classified as an SAE which is related to the trial treatment and is unexpected in terms of the events listed in the protocol.

In the case of discrepant views on causality between the Investigator and others, Southern Health will classify the event as per the worst case classification I and where applicable the Ethics Committee will be informed of both opinions within the required timelines.

13.4. Expectedness

Expectedness assessments are made against the list of expected events below:

Expected Adverse Events:

- Minor musculoskeletal aches and pains
- Known adverse effects of medications used in the intervention.

The nature or severity of should be considered when making the assessment of expectedness. If these factors are not consistent with the current information available, then the AE should be recorded as 'unexpected'.

13.5. Reporting Procedures

All adverse events should be reported. Depending on the nature of the event, the appropriate reporting procedures below should be followed. A flowchart will be provided to aid in the reporting procedures.

Reporting Details

A SAE for Non-CTIMPs Form should be completed for all SAEs and emailed to Southern Health within 24 hours of site becoming aware of the event. Complete the SAE form and email a scanned copy of the form with as many details as possible to Southern Health together with anonymised relevant treatment forms and investigation reports.

Or

Contact Southern Health by phone for advice and then email a scanned copy of the completed SAE form.

SAE REPORTING CONTACT DETAILS

Please email a copy of the SAE form to

Southern Health within 24 hours of becoming aware of the event

Email: peter.phiri@nhs.net

Additional information should be provided as soon as possible if the event has not resolved at the time of reporting.

Follow Up and Post- study SAEs

The reporting requirement for all AEs and SAEs affecting participants applies for all events occurring up to 7 days after the last treatment. All unresolved adverse events should be followed by the investigator until resolved, the participant is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator should instruct each participant to report any subsequent event(s) that the participant, or the participant's general practitioner, believes might reasonably be related to participation in this study. The investigator should notify the study sponsor of any death or adverse event occurring at any time after a participant has discontinued or terminated study participation that may reasonably be related to this study.

Non-serious AEs

All adverse events should be recorded in the relevant eCRF and submitted to Southern Health.

Pre-existing Conditions

Medically significant pre-existing conditions (those which are present prior to informed consent) should not be reported as an AE unless the conditions worsens during the trial. The condition, however, must be reported on the Medical History eCRF. Any adverse events which occur after informed consent taken should be recorded on the AE eCRF as per safety reporting section.

Serious Adverse Events

All SAEs should be reported within 24 hours of the local site becoming aware of the event. The SAE Non-CTIMP Form asks for nature of event, date of onset, severity, corrective therapies given, outcome, causality (i.e. unrelated, unlikely, possible, probably, definitely) and expectedness. The responsible investigator should assign the causality and expectedness of the event with reference to the events listed. The event term should be in accordance with the latest version of MedDRA and grades given in accordance with the NCI CTCAE v4.03, Additional information should be provided as soon as possible if the event has not resolved at the time of reporting.

Southern Health Responsibilities for Safety Reporting to REC

Southern Health will notify the necessary competent authorities of all **Related and Unexpected** SAEs occurring during the study within 15 days. Southern Health will submit all safety information to the REC in annual progress report.

13. ETHICAL AND REGULATORY CONSIDERATIONS

13.1.Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

13.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

13.3. Approvals

Following Sponsor approval, the protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA (where required) and host institutions for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

13.4. Other Ethical Considerations

The study will be conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 as revised and recognised by governing laws and EU Directives. Each participant's consent to participate in the study should be obtained after a full explanation has been given of treatment options, including the conventional and generally accepted methods of treatment. The right of the participant to refuse to participate in the study without giving reasons must be respected.

After the participant has entered the study, the clinician may give alternative treatment to that specified in the protocol, at any stage, if they feel it to be in the best interest of the participant. However, reasons for doing so should be recorded and the participant will remain within the study for the purpose of follow-up and data analysis according to the treatment option to which they have been allocated. Similarly, the participant remains free to withdraw at any time from protocol treatment and study follow-up without giving reasons and without prejudicing their further treatment.

Informed consent is a process that is initiated prior to an individual agreeing to participate in a study and continues throughout the individual's participation. In obtaining and documenting informed consent, the investigator should comply with applicable regulatory requirements and should adhere to the principles of GCP.

Discussion of objectives, risks and inconveniences of the study and the conditions under which it is to be conducted are to be provided to the participant by appropriately delegated staff with knowledge in obtaining informed consent with reference to the patient information leaflet. This information will emphasise that participation in the trial is voluntary and that the participant may withdraw from the trial at any time and for any reason. The participant will be given the opportunity to ask any questions that may arise and provided the opportunity to discuss the study with family members, friend or an independent healthcare professional outside of the research team and time to consider the information prior to agreeing to participate.

13.5. Reporting

The CI shall submit on request, and at the end of the year an Annual Progress report to the REC Committee, HRA and to the NHS Sponsor and funder as required. Furthermore, the CI will submit the End of Study notification and final report will be submitted to the same parties.

13.6. Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018. Southern Health will preserve the confidentiality of participants taking part in the study. The investigator must ensure that participant's anonymity will be maintained and that their identities are protected from unauthorised parties. On CRFs participants will not be identified by their names, but by an identification code. All documents will be stored securely and only accessible by study team and authorised personnel.

13.7. Expenses and Benefits

Participants will not be reimbursed in this study.

14. FINANCE AND INSURANCE

14.1.Funding

Dexcom Inc. no-cost CGM devices and supplies.

14.2. INDEMNITY

For NHS sponsored research HSG (96) 48 reference no.2 applies. If there is negligent harm during the clinical study when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the study. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

14.3. Contractual Arrangements

Appropriate contractual arrangements will be put in place with all third parties.

15. PUBLICATION/DISSEMINATION POLICY

Data from all centres will be analysed together and published as soon as possible. Individual investigators may not publish data concerning their patients that are directly relevant to questions posed by the trial until the Trial Management Group (TMG) has published its report. The TMG will form the basis of the Writing Committee and advise on the nature of publications. All publications shall include a list of investigators, and if there are named authors, these should include the Chief Investigator, Co-Investigators, Trial Manager, and Statistician(s) involved in the trial. Named authors will be agreed by the CI and Director of Southern Health. If there are no named authors then a 'writing committee' will be identified.

16. Innovation / Scalability and Route to Implementation (Market)

Spotlight Consultations digital health tools are innovative and unrivalled. They are scalable to different national and international health services, transferable into different languages (currently English, Mandarin and Spanish) and contain in-built audio/colour versions for people with low literacy. The route to the UK NHS market access involves the current efficacy and cost-effectiveness RCT within the Health Technology assessment (HTA) process. Positive results will enable Spotlight Consultations tools to be rolled out across CCGs. In addition, partnering with global companies with established routes to market will enable our tools to access global marketing

networks and we are in discussions with one such global company currently. Further research to adapt the tools to US and China/Taiwain/Singapore markets are planned based on the results of the current study.

16.1. Value for Money Statement

This trial represents excellent value for money. Every effort has been made to keep costs to a minimum. We have sought to collaborate where possible to ensure the intervention is transferable to the broader community in terms of diversity, socio-economic status and health literacy implications. Furthermore, the intervention can be adapted to other chronic conditions such as cardiovascular disease, chronic pelvic pain, irritable bowel disease and some cancers.

17. ARCHIVING

Study documentation will be archived in accordance with guidelines for Good Clinical Practice and in NHS approved, secure and adequate archiving facility. Research personnel will keep information relevant to the study for up to 10 years, and then will be destroyed.

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APPENDIX A: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made