FULL/LONG TITLE OF THE STUDY
SfE CORE Study: Clinical Observations and Research on Engagement in Specialist Weight Management Services.

SHORT STUDY TITLE / ACRONYM
SfE CORE Study

PROTOCOL VERSION NUMBER AND DATE
3 12 February 2026

RESEARCH REFERENCE NUMBERS

IRAS Number:	351656
SPONSORS Number:	SfECORE2025
FUNDERS Number:	N/A

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 also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that 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):

.....

Position:

.....

Principle Investigator:

Signature: Date:

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

Name: (please print):

.....

LIST of CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Prof Rob Andrews Tel: +44 (0)1823 344132 Email: R.C.Andrews@exeter.ac.uk
Study Manager	Grace Okoro Society for Endocrinology Starling House | 1600 Bristol Parkway North | Bristol | BS34 8YU | UK Tel: +44 (0)1454 642251 Email: research@endocrinology.org
Sponsor	Jessica Davis Society for Endocrinology Starling House | 1600 Bristol Parkway North | Bristol | BS34 8YU | UK Tel: +44 (0)1454 642251 Email: research@endocrinology.org
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	Education grants from Novo Nordisk, Rhythm and Boehringer Ingelheim
Key Protocol Contributors	Dr Luke Boyle Dr Sadaf Ali Professor John Wass
Committees	Study Steering Committee Professor John Wass (Chair) Professor Rob Andrews Dr Adrian Park Dr Karen Coulman Sarah LeBroq – patient liaison to Obesity Health Alliance Danielle Wigg Dr Ian McKenna Dr Amanda Peacock Dr Sadaf Ali Dr Grigorios Panayiotou Dr Petra Hanson Irena Cruickshank Dr Ahmed Al-Marbeh Dr Imad Mekhail Dr Luke Boyle

STUDY SUMMARY

Study Title	SfE CORE study: Clinical Observations and Research on Engagement in Specialist Weight Management Services.
Internal ref. no. (or short title)	SfE CORE Study
Study Design	Observational cohort study
Study Participants	Patients attending Specialist Weight Management Services (or equivalent services) NHS obesity clinics in England and Wales.
Planned Size of Sample (if applicable)	To get half of the weight management services to collect data from 60% of patients attending their weight management service.
Follow up duration (if applicable)	For as long as in the weight management service, average time for this is 18 months.
Planned Study Period	48 Months
Research Question/Aim(s)	To understand the demographic and clinical characteristics of the people who attend the specialist weight management services and how they respond to the treatments that they are offered.

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
Novo Nordisk	Education grant to do study in weight management
Rhythm Pharmaceuticals	Education grant to do study in weight management
Boehringer Ingelheim	Education grant to do study in weight management

ROLE OF STUDY SPONSOR AND FUNDER

The Society of Endocrinology is the sponsor of the study. The sponsor will be responsible for initiation and management of the study, and the data ownership. Though, the sponsor controls the final decision regarding these aspects of the study. The sponsor will help with dissemination of the results.

Novo Nordisk, Rhythm Pharmaceuticals and Boehringer Ingelheim have provided financial support for this study. They will not play a role in data analysis interpretation, manuscript writing or dissemination of the results. Support from these companies will be acknowledged in manuscripts resulting from this work.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

On this project there will be a Study steering committee and patient and public involvement group.

The study steering committee, chaired by a Consultant Endocrinologist, will meet up to 3-4 times a year to:

- Suggest any changes to the data being collected (which if made will be made after ethical approval).
- Suggest sites which would be suitable to participate in the collation of data
- Sign off on the yearly annual report.
- Determine who is able to have access to the anonymised data generated by the Database
- Consider whether additional projects can be tied to this database.
- Oversee the management of the budget for the project provided by external funders, held at the Society for Endocrinology

The patient and public involvement group will meet two times a year to:

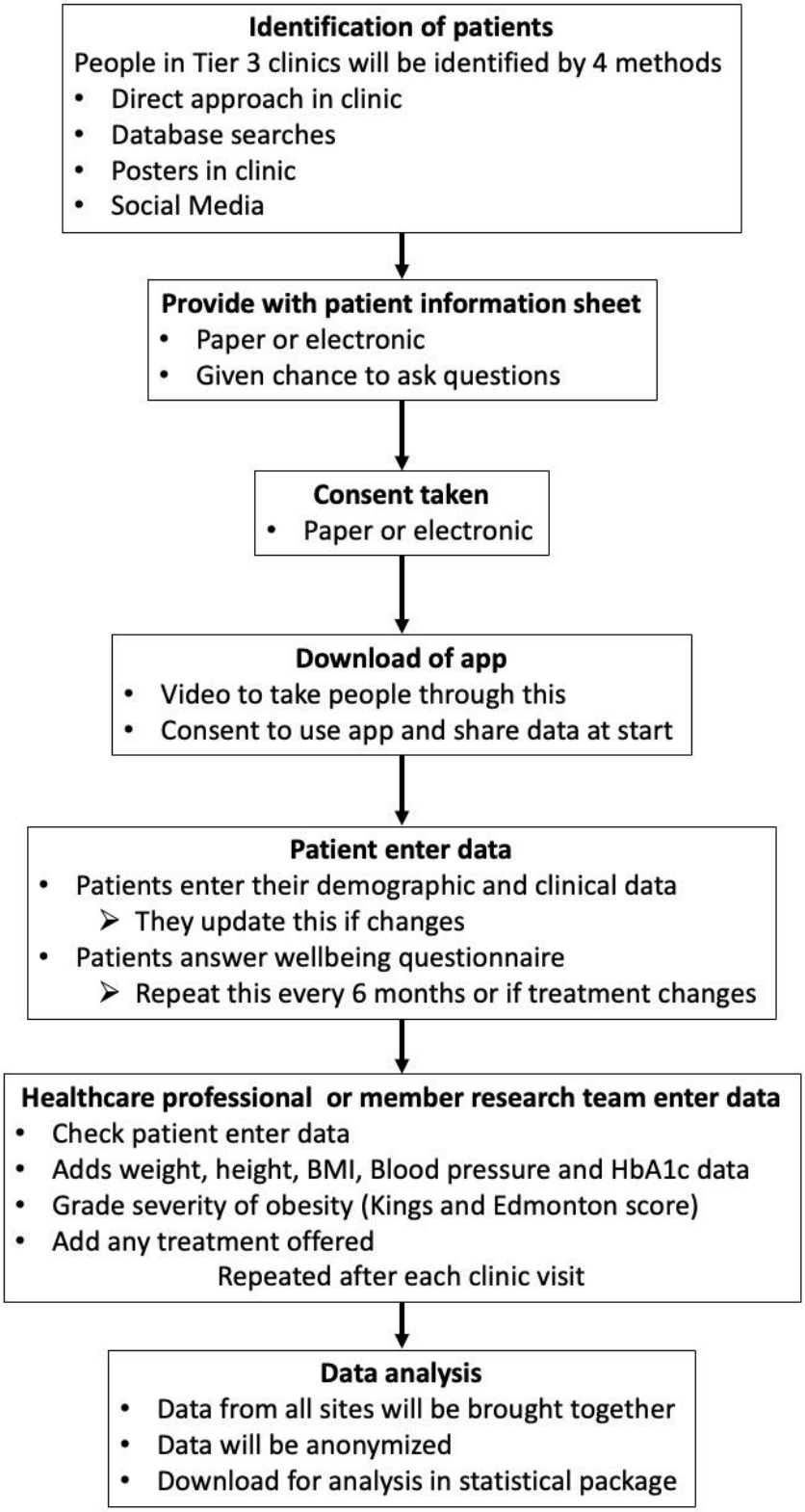
- Suggest any changes to the data being collected or the way in which we do this if patients are describing difficultly with using the app (which will only be after ethical approval).
- Suggest what changes could be made to our method of recruitment if we are struggling to engage patients.
- Help with news letters to patients involved in the study.
- Comment on the yearly annual report.
- Comment on any results that are obtained.
- Help wih publications and producing literature explaining the results of the study to patients and the public.

PROTOCOL CONTRIBUTORS

This protocol has been designed with help of the study steering committee, South East London Patient Support Group,and the study sponsor. The funders have had no role in designing the protocol.

KEY WORDS: Obesity
Specialist weight management services
Observation study
Clinical outcomes
Patient reported outcomes

STUDY FLOW CHART



STUDY PROTOCOL

SfE CORE study: Clinical Observations and Research on Engagement in Specialist Weight Management Services.

1 BACKGROUND

Obesity is an escalating issue in the UK, which currently has the highest obesity rate in Europe [1]. Approximately 27% of the adult population is classified as obese, contributing significantly to the primary care workload, with obesity associated with 44% of Type 2 diabetes cases, 23% of ischaemic heart disease cases, and 41% of certain cancer types [2]. Notably, the prevalence of severe obesity—an important factor in reduced life expectancy—has doubled over the past decade, affecting approximately 2.6 million adults [2].

The current framework for obesity management in the UK consists of a four-tier model. Tier 1 focuses on prevention and is managed by Public Health initiatives. Tier 2 services are community-based, providing referrals to evidence-based lifestyle interventions such as Weight Watchers and the Counterweight Programme. Individuals in Tier 2 typically have a BMI of 28-35 and do not present with complex medical issues. Tier 3 services or specialist weight management services represent a multidisciplinary specialist approach, available in community, primary or secondary care settings. This tier caters to individuals with a BMI greater than 35 (or over 30 if they have diabetes) and complex medical conditions, offering pharmacotherapy, low-energy liquid diets, and pre- and post-bariatric surgery care. Tier 4 services, located within secondary care, focus on bariatric surgery.

Data on obesity rates are systematically collected by the National Audit Office, enabling monitoring of Tier 1 effectiveness. Additionally, the National Bariatric Database provides insights into bariatric surgery rates, patient characteristics, and surgical outcomes [3]. However, comprehensive data on Tier 3 or specialit weight management services remain scarce, with information primarily available from only 4 of the 42 tier 3 clinics. Consequently, it is challenging to ascertain the availability of Tier 3 services across different regions, the volume of referrals, the demographics of individuals accessing these services, and their outcomes during treatment. This lack of data hinders our ability to evaluate equitable access, appropriate referrals, and the overall effectiveness of these services throughout the UK.

Objectives of the CORE Study

Our primary objective is to establish a study that will compile data from weight management services, focusing on the following key areas:

1. **Demographics:** Age, sex, socioeconomic status (derived from postcode), ethnicity, marital status and employment status and Job.
2. **Weight History:** Weight at significant life milestones (birth and leaving school), onset of weight issues, highest and lowest adult weight, weight changes over the past five years.
3. **Previous Weight Loss Attempts:** History of interventions and weight loss with these.
4. **Medical Conditions:** List of medical conditions with dates started. Severity of these medical conditions will be assessed using the Kings score and Edmonton score.
5. **Medication:** Details on dosage and frequency and when started on these drugs.

6. **Patient-Reported Outcomes:** Quality of life (EQ5D questionnaire) and well-being (BodyQ questionnaire).
7. **Clinical Treatments:** Interventions received during clinic visits.
8. **Clinical Measures:** Weight, height, BMI, blood pressure.
9. **Relevant Laboratory Results:** HbA1c if has diabetes.

The information gathered through this study will serve to enhance productivity in existing services, inform business planning, and support the establishment of new services. It will also provide critical data to ensure equitable access to weight management services nationwide. Furthermore, the database will function as a registry, enabling researchers to apply for access to data that will advance our understanding and treatment of obesity.

Study Aim: This study aims to demonstrate proof of concept for our new data collection system involving a network of weight management clinics across England and Wales. Success would be seen in getting 50% of the current specialist weight management services (there are approximately 49 services at the moment[4]) to capture data on 60% of the patients attending their clinics. Focusing on specialist weight management services in the first instance and then rolling out to other primary care services in a second phase.

2 RATIONALE

As mentioned above there is very little data on who attends specialist weight management services and how effective the interventions offered in these clinics are. This study will enable us to say

1. Whether there is equal access to treatment based on sex, age, social class and ethnicity and if not start to work out what we can do to ensure this does happen.
2. The characteristics of the people attending the specialist weight management services. This data will give an insight as to how unwell this population is and how many people are being referred to these services which will help with planning of services.
3. How effective these services are and whether this varies from area to area. If we find specific models that are working well we can highlight these to the other clinics.
4. Some insight into the “real world” effectiveness of different types of interventions. This is particularly important with two new obesity drugs now being offered on the NHS.

3 RESEARCH QUESTION/AIM(S)

This study aims to demonstrate proof of concept for our new data collection system involving a network of specialist weight management service across England and Wales. Success would be seen as getting 50% of the current specialist weight management services [4] to capture data on 60% of the patients attending their clinics

3.1 Objectives

1. To get 50% of specialist weight management services that exist in England and Wales to collect data on patients that attend their weight management clinics.

2. For the centres entering data to capture data on 60% of the patients attending their clinics.

3. To compare the data entered by 100 patients to that collected by a doctor in their initial interview. This will validate that data entry by patients is reliable.

4. To demonstrate that key outcomes are captured in sufficient quantity to give a fair representation of the people attending the clinics.

5. To describe the demographics and clinical characteristics of people attending the specialist weight management services who sign up to the study.

6. To look at changes in weight and well-being over the time in clinic and whether this is affected by treatment modality.

7. To explore potential disparities in access to specialist weight management services based on demographic factors (e.g., ethnicity, socioeconomic status).

8. To explore potential disparities in outcomes from specialist weight management services based on demographic factors (e.g., ethnicity, socioeconomic status).

9. To explore this methodology in collecting data on these characteristics from those patients who attend weight management services in primary care settings.

3.2 Outcomes

	Objectives	Outcome Measures	Timepoint(s)
Primary	To demonstrate that our system can be integrated into specialist weight management services clinics and collect data on patients attending clinics.	The number of clinics using the system by end of year 2 of the project. Our aim would be to have 50% of specialist weight management services using this system.	24 months
Secondary	To demonstrate that key outcomes are captured in sufficient quantity to give a fair representation of the people attending the clinics	That the clinics on average are collecting data on 60% of the patients that attend their clinics and on these they have at least 80% data on our key outcomes which are **Demographics** Age, sex, socioeconomic status, ethnicity, marital status and employment status and Job.	Baseline Baseline

		Weight history Birth weight, age weight problem started at, highest and lowest weight. Current weight.	Baseline
		Previous Weight Loss Attempts *Previous Bariatric surgery* – Y/N – if Y when and Type. *Attempts at commercial diets*- Y/N if Y when and Type *Tried weight loss* medication – Y/N if Y when and Type	Baseline and every 12 months until leaves clinic.
		Medical and drug history List of medical problems with date started. List of drugs taking with dose, frequency and start date.	Baseline and every 12 months until leaves clinic.
		Clinical Treatments *Diet and Exercise advice* Y/N if yes details and date offered *Low calorie diet* Y/N if yes details and date started and finished. *Specific help with eating habits* Y/N, If yes details and date (S) delivered *Sessions with psychologis* Y/N, If yes details and date (s) delivered. *Weight loss drugs* Y/N if yes which type and when started. *Referred for surgery* Y/N if yes when.	Baseline and every 12 months until leaves clinic.
		Patient-Reported Outcomes EQ5D and Body Q	Baseline and every 12 months until leaves clinic.
		Clinical Measures Weight, height, BMI, blood pressure.	Baseline and every 12

		Relevant Laboratory Results: HbA1c if has diabetes.	months until leaves clinic.
Exploratory	Demographic and clinical characteristics of people attending clinics. To look at changes in weight and well-being over a year and whether this is affected by treatment modality To explore potential disparities in access to specialist weight management service based on demographic factors (e.g., ethnicity, socioeconomic status). To explore potential disparities in outcomes from specialist weight management service based on demographic factors (e.g., ethnicity, socioeconomic status). To explore the outcomes and data collection within primary care additional to specialist weight management services.	All key measures mentioned above *Changes in Weight and Wellbeing* - Weight, BMI, EQ5D and Body Q scores changes over 12 months. Comparison of these changes between different treatment modalities. *Access Disparities:* Assess whether certain demographic groups are underrepresented in specialist weight management services *Outcome Disparities:* Analyse differences in clinical outcomes across various demographic subgroups Expectation: building for the future with expectations of services potentially moving from secondary/tertiarty care to primary care sites especially in the role of GLP1 treatments	Baseline Baseline and every 12 months. Baseline and every 12 months. Baseline and every 12 months.

4 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

Study Design

This is a multicentre observation study of people attending a specialist weight management service. Data will be collected from two sources

1. the patient who is attending the weight management clinic – they will enter data into a phone app called Peoplewith (http://peoplewith.com). This will be the primary source of the data.

2. Weight management services - Healthcare professionals or those with delegated access per site will input data into the clinician portal of the peoplewith app. The data entered will be routine data that is already collected in the clinic.

This study will involve no intervention, no additional clinical visits or changes to care, and no change to usual behaviour or routine.

Data collection

Patients will be recruited from weight management services, specialist weight management service in the first instance, via informed electronic consent. Those patients interested in being involved with the study will download an app (*PeopleWith*). Through this app they will learn more about the study and consent to be involved. Once they have consented to being involved, they will be asked to fill in demographic and clinical data on the app and complete some questions. The following data will be collected.

1. **Demographics:** Age, sex, socioeconomic status (derived from postcode), ethnicity, marital status and employment status and Job.
2. **Weight History:** Weight at significant life milestones (birth and leaving school), onset of weight issues, highest and lowest adult weight, weight changes over the past five years.
3. **Previous Weight Loss Attempts:** History of interventions and weight loss with these.
4. **Medical Conditions:** List of medical conditions with dates started. Severity of these medical conditions will be assessed using the Kings score and Edmonton score.
5. **Medication:** Details on dosage and frequency and when started on these drugs.
6. **Patient-Reported Outcomes:** Quality of life (EQ5D questionnaire) and well-being (BodyQ questionnaire).
7. **Clinical Treatments:** Interventions received during clinic visits.
8. **Clinical Measures:** Weight, height, BMI, blood pressure.
9. **Relevant Laboratory Results:** HbA1c if has diabetes.

Every 3 months patients will be prompted to update their records. Patient reported outcomes will be repeated every 12 months or when treatment is changed. See table below explaining in more detail about how the app collects data.

App Registration	New Symptom/Treatment Added	Notifications to Patients
Upon registration there will be a series of mandatory health related data points for the patient to complete	If a patient adds in a new symptom or treatment this will trigger the opportunity to complete a new EQ5D and BodyQ.	Patients will be reminded by notification of the mandatory data points if they have not been completed within 2 weeks of registration
Upon registration there will be available health related data points which are not mandatory for the outcomes of the project, however, there is the opportunity for the patients to		If a patient adds in a new symptom or treatment this will trigger the opportunity to complete a new EQ5D and BodyQ.

engage more in their health care by using the entirety of the app.		
EQ5D and Body Q questionnaire will be available for the patient to complete		Every 3 months patients will be prompted to update their information
Patient support groups pertinent to the care of these patients will be highlighted on a separate tab in the app		

Data from clinic appointments will be entered by healthcare professionals or those with delegated access per site. These people will will be check the data that the patient has put in and correct if mistakes have been made. In addition, they will enter weight, height and blood pressure readings from the clinic appointments, HbA1c if measured and details on any treatments offered. Finally, they will assess the severity of the patient's medical health using the Kings and Edmonton scores and record this on the *PeopleWith* dashboard. This data entry will be repeated after each clinical visit.

Data analysis

The primary outcome of this study is the number of clinics collecting data. Are aim is to get 50% of specialist weight management service using the database. We will report the number of specialist weight management service and what percentage of clinics are using the app at year 2 of the project.

The secondary outcomes of this study are the percentage of patients who we capture data on, and the percentage of data captured on key variables. Our aim to capture data on 60% of patients who attend the services and of those who sign up to the study aim to capture key data on 80% of these patients. The percentage of people we capture the data on will be = (the number of people we have data on/the number of people who attend the clinic) X 100. The percentage of key variable will be worked out for each variable and will be = (number of variable entered/ number of variable possible) x 100.

For the exploratory analysis we will use simple stats (mean, median, SD, interquartile ranges and percentage) to describe the demographic and clinical characteristics of the people entered into the database. Multivariable linear regression will be used to look at the change in weight, BMI, EQ5D and Body Q scores over 12 months and to determine if this is influenced by treatment modality and demographic groups. All analysis will be done in STATA.

5 STUDY SETTING

Study data will be collected from NHS trusts that have an adult weight management services. The names of these NHS trust are

- Somerset NHS Foundation Trust
- Addenbrooke's Hospital
- Royal United Hospital Bath

- St George's University Hospitals NHS FT
- Swansea Health Board
- South Tyneside and Sunderland NHSFT
- Imperial College London
- University Hospitals Coventry and Warwickshire
- Worcester Acute Hospitals Trust
- Barnsley Hospital NHS Foundation Trust
- Chelsea and Westminster NHS Foundation Trust
- Great Western Hospital
- Countess of Chester Hospital NHS Foundation Trust
- North Cumbria Integrated Care NHS FT

Data collection at each site will be identical. Additional sites will be added as an amendment.

6 SAMPLE AND RECRUITMENT

6.1 Eligibility Criteria

Any patients that attend a specialist weight management service that has signed up to take part in this study will be eligible to be entered into this study.

6.1.1 Inclusion criteria

1. Patient is willing and able to give informed consent for the participation in the trial.
2. Over the age of 18.
3. Patient, in the investigator's opinion, is able and willing to comply with all the study requirements.
4. Patient is seen in a specialist weight management service across the England and Wales
5. Patient is willing and able to download an application in the English language

6.1.2 Exclusion criteria

1. Patients unable to give informed consent. This will be determined by the principle or sub investigator as to the patient's capacity at the time of informed consent.

6.2 Sampling

We will aim to recruit all patients who attend specialist weight management service in England and Wales (Scotland are exploring a different mechanism for collecting data from their specialist weight management service).

6.2.1 Size of sample

We have not conducted a formal power calculation for this study. The primary objective is to evaluate whether this database can collect sufficient data from specialist weight management service to develop a national profile of patients attending these clinics, the treatments provided, and the effectiveness of these treatments. Previous efforts to collect data from these clinics have been limited

in scope, falling short of achieving a comprehensive national overview. Should this project succeed in gathering adequate data, this system will be commissioned as the NHS-standard platform for such data collection.

Our target is to engage 50% of specialist weight management service to use this system and capture 80% of essential data points for 60% of patients attending these clinics. Each weight management service typically receives approximately 700 patient referrals annually, with patients spending an average of 18 months in the program. We plan to recruit patients for two years, tracking outcomes for the duration of their clinic attendance. Data entry can be retrospective, allowing us in the first year to gather data on approximately 1,050 existing patients (700 * 1.5) and 700 newly referred patients each in the first and second years, leading to a potential recruitment of 2,450 patients per service.

Assuming an 80% capture rate, we anticipate enrolling 1,960 patients per clinic, resulting in a total of 41,160 patients across 21 participating sites.

6.2.2 Sampling technique

This will be convenience sampling with all patients attending the specialist weight management service soffered to enter the study.

6.3. Recruitment

6.3.1 Patient identification

Staff (clinical and research team) from the sites (both secondary and primary care services) and patient identification centres that have agreed to take part in the study will identify and approach all patients. There will be five recruitment strategies

Recruitment through direct approach; In clinic healthcare professionals will describe the study to patients and provide them with written or electronic information about the study dependent on the request of the patient. The patients can also be sent the invitation letter. Permission will be obtained to contact them a few days later by phone to see if they are interested in participating. Those interested in participating will be given the opportunity given to ask questions, and consent obtained.

Database search: Local databases will be used to identify patients attending or on the waiting list to be seen in the local specialist weight management service or primary care service. These people will be sent information about the study and those interested will be asked to contact the study team.

Poster: A poster with information about the study will be sited in the waiting rooms of hospital outpatient. This poster will have a ‘tear- off’ contact telephone number and email address for the study investigators as well as a QR code for downloading all information about the study. Those interested will be able to discuss the study with the local research team and ask questions.

Social media: We will also advertise the study on social media such as X and facebook and place information on hospital internets and diabetes websites. In addition, we will access the Trusts involved, NIHR and UKCRN communication leads to promote the study via social media and newsletters.

Patient Identification Centres (PIC): weight management services which have primary care services embedded as part of their trusts infrastructure may use these primary care services as PIC sites, provided a local contract is in place. The use of the approved invitation letter and patient flyer can be used for this instance.

Be Part of Research: The purpose of the Be Part of Research Volunteer Service (BPORVS) is to allow members of the public to become volunteers by creating an account, specifying the areas of research that they are interested in and give consent to be contacted by the Be Part of Research team. Those who consent will receive information about BPORVS, in particular to alert them to specific BPORVS registered studies that they may be interested in, based on their volunteered details and study specific eligibility criteria, using an online self-registration service. The register is open to those that live in the UK, are over 18 and have an email address.

At the time of registration, volunteers are made aware that they are not signing up to take part in a specific health study when they join this register and that they will only be signposted to studies that have NIHR funding or are listed on the NIHR RDN Portfolio. If the volunteer is interested in the study there will be a link in the email to take them to the study team (e.g. website, pre-screener) where they will move into the study teams screening process and consenting process if they take part in the study.

The Be Part of Research Volunteer Service is funded by the Department of Health and Social Care and delivered by the National Institute for Health and Care Research (NIHR) in conjunction with Public Health Agency, Research & Development, Northern Ireland, NHS Scotland and Health and Care Research Wales.

Further information on the Be Part of Research Volunteer Service is available here:

https://bepartofresearch.nihr.ac.uk/researchers-and-health-and-care-professionals/information-for-researchers/recruit-to-your-study/

6.3.2 Consent

Regardless of the method of patient identification, the interested participants will be provided with a Participant Information Sheet (PIS) by a member of their clinical or research team. Two versions of the PIS will be available: a printed version or an electronic version.

The participant must personally sign and date the latest approved version of the Informed Consent form before any trial specific procedures are performed.

Written, electronic, and verbal versions of the participant information and informed consent form will be presented to the participants detailing no less than: the exact nature of the trial; what it will involve for the participant; the implications and constraints of the protocol; the known risks involved

in taking part. It will be clearly stated that the participant is free to withdraw from the trial at any time for any reason without prejudice to future care, and without affecting their legal rights and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the trial. Written or electronic informed consent will then be obtained by means of participant dated signature and dated signature of the person who obtained the informed consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. The Chief Investigator or Principle Investigator that assigns personnel to be suitably qualified in obtaining informed consent must assess the research CV of the individual prior to sign off to make sure that appropriate local informed consent training has been undertaken, this can be in the case of the principle investigator assessing capability during clinic and then appointing the personnel to the delegation log after this time. A copy of the signed informed consent form will be given to the participant or stored within the application.

The e-consent will be able to track the version of informed consent and patient information sheet by methods detailed. The Consent Form presented within the *PeopleWith* study application is aligned to the Patient Identification Key, which is entered once the app is downloaded. The *PeopleWith* E-Consent model links the Consent Form and Patient Information Sheet via unique document identifiers. Each version of the Consent Form and Patient Information Sheet are assigned a unique identifier with version control maintained (i.e. version number, timestamp). Version details are displayed on each document.

The Patient Information Sheet is made available to the participant prior to providing e-consent. Each participant is required to confirm that they have read the Patient Information Sheet prior to completing study onboarding. Upon completing the consent process, a timestamped record is created, linking the unique document identifiers and electronic signature with the participant identification key to provide an audit trail.

Participants who provide consent to take part in the study are presented within the investigator site dashboard, with a copy of the e-consent, providing the Investigators with the opportunity to review and validate the participant.

7 ETHICAL AND REGULATORY CONSIDERATIONS

The primary ethical considerations for this study are described below:

Consent: Participation in this study at all sites will require consent. In this study consent will be sought only after the participant has received an information sheet, been given adequate time to consider participation, and had the opportunity to ask the research team any questions they may have. Signed informed electronic consent will be obtained from all participants. The right of the participant to refuse participation without giving reasons will be fully respected. Participants may withdraw from the study at any time, although data already collected will not be withdrawn, as the link to personal data will have been anonymized.

***Confidentiality*:** The research team will maintain the confidentiality of all participants in the study, following the General Data Protection Regulation (GDPR) and Data Protection Act. Within the peoplewith App personal data will be recorded and each site, on the clinician platform will be able to see data on participants from their site who have consented to be in the study. The peoplewith app and clinician platform is certified under the ISO-9001 quality assurance and ISO-27001 information security standards. Peoplewith also Hicom own and manage their own data centre in the UK with 24-hour security and off-site disaster recovery provision. So, they meet all the NHS IT, data protection and governance requirements. There will be no paper records for this study.

When data is taken out of the Peoplewith app for analysis the data will be anonymised and no identifiable data retained, and each person will be allocated a specific number. This data will be stored will be stored on a networked PC in a password-protected document. Following completion of the study the pseudonymised data will be stored on a network attached data storage system used only by the society of endocrinology. Access to this storage system will be restricted to the principal investigator and authorised research team members, with entry controlled via personal login credentials and password protection.

Any reports, presentations or publications will contain no identifiable data.

***Data protection/data storage*:** All data collected will be anonymized, and analysis will take place on a password-protected computer. All documentation will be stored securely for 15 years following the completion of the study. After 10 years, all online data will be securely erased.

Declaration of Helsinki: The Investigator will ensure that this trial is conducted in accordance with the principles of the Declaration of Helsinki. NB. The 2008 Declaration of Helsinki provides detail on what must be included in a protocol: funding, sponsorship, affiliations and potential conflicts of interest, incentives to participate, compensation for harm and post-trial access to drugs and care.

Guidelines for Good Clinical Practice: The Investigator will ensure that this trial is conducted in accordance with relevant regulations and with Good Clinical Practice.

Approvals : Following Sponsor approval, the protocol, informed consent form, participant information sheet will be submitted to an appropriate Research Ethics Committee (REC), HRA and NRSPCC (Scotland only) (where required), and host institution(s) 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.

Other Ethical Considerations: Data will be sourced from secondary care institutions or electronic data capture systems.

Reporting: The CI shall submit once a year throughout the clinical trial, or on request, an Annual Progress Report to the REC, HRA (where required), host organisation, funder (where required) and Sponsor. In addition, an End of Trial notification and final report will be submitted to the REC, host organisation and Sponsor.

Expenses and Benefits: There will be no cost reimbursed for participation in the study. Patients data will be collected at routine visits to the clinic or hospital so there are no expected additional costs to patients who choose to participate

7.1 Assessment and management of risk

This study will involve no intervention, no additional clinical visits or changes to care, and no change to usual behaviour or routine. Patients will simply be recording their medical details in an app (people with) and clinicians will be adding data routinely collect in clinic to the app through the clinician's portal. As such the risks of participating are minimal.

7.2. Research Ethics Committee (REC) and other Regulatory review & reports

- Prior to the start of the study, approval will be sought from an NHS Research Ethics Committee (REC) for the study protocol, informed consent forms, and other relevant documents such as advertisements.
- Any amendments or changes to the study status will be submitted for approval to the REC that initially approved the study and any other relevant regulatory authorities.
- All correspondence related to the study will be carefully retained.
- The protocol, informed consent form, participant information sheet, and any proposed advertising materials will be submitted to the Health Research Authority (HRA) for written approval.
- Study Progress Reports will be submitted to the NHS REC that granted the favourable opinion, the HRA (via hra.approval@nhs.net), and the Sponsor (via research@endocrinology.org) on the anniversary of the REC's favourable opinion, as necessary.
- Upon completion of the study, an End of Study Declaration (within 90 days of the study's conclusion) and an End of Study Report (within 12 months of the study's conclusion) will be submitted to the NHS REC that granted the favourable opinion and to the society of endocrinology (research@endocrinology.org).

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place.

Amendments

Any such deviations from the above protocol will be properly documented using the relevant forms and promptly reported to the Chief Investigator and Sponsor. Repeated deviations from the protocol are unacceptable, will require immediate corrective actions, and may be classified as a serious breach. Any serious breaches will be communicated to the Sponsor via email.

The quality and integrity of the study will be maintained through regular management meetings. The Local Delivery Group, consisting of the Chief Investigator, Rob Andrews, sponsor representative and

study coordinator, and selected members of the Steering Group will hold quarterley meetings to discuss study progress.

7.3 Peer review

Funding from Novo Nordisk, Rhythm Pharma, and Boehringher Ingleheim was allocated through an education grant. To obtain this the project went through a peer review process and then was awarded the grant by a grant giving committee.

7.4 Patient & Public Involvement

The premise and rationale for this research stems from a meeting with adults with obesity and families where it was highlighted that without data on who was attending weight management clinics and the effectiveness of these clinics it was unlikely that we would get further funding to increases services. It is clear that addressing this is a priority.

Values and experiences of those living with obesity diabetes will be integrated throughout the project. We have formed and are working with a patient advisory group of 6 people in various ways, with flexibility to address any emerging issues, including: 1) Development of this protocol and study documentation including participant information, 2) refinement of the Peoplewith app and what data we collect, 3) Interpretation of study findings from, 4) dissemination of the finding of this study.

7.5 Protocol compliance

Risk Assessment and Monitoring
The trial will be conducted in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures. A risk assessment and monitoring plan will be prepared before the study opens and will be reviewed as necessary over the course of the trial to reflect significant changes to the protocol or outcomes of monitoring activities.

Regular monitoring will be performed according to the trial specific monitoring plan. Data will be evaluated for compliance with the protocol and accuracy in relation to source documents as these are defined in the trial specific monitoring plan. Following written standard operating procedures, the monitors will verify that the clinical trial is conducted and data are generated, documented and reported in compliance with the protocol, GCP and the applicable regulatory requirements.

All monitoring reports will be reviewed by the trial steering committee in their regular meetings and action taken if needed to deal with protocol deviation and any other issues. Day to day the CI will be available to deal with any urgent issues that come up.

Definition of the end of trial
The definition of the end of the data collection of the study will be when the timepoint of 24 months of recruitment and then 6 months following this date is reached. Data on patients at their routine

clinic appointments will be collected up until this date but not after. Once all the data is collected and all queries are answered the study will remain open for data analysis but not the addition of data.

Safety reporting
There is no study investigational medicinal product or other product being used so there are no safety triggers or reporting for this study. There is no need to record adverse events, adverse reactions, suspected unexpected serious adverse reactions, or serious adverse events during the course of the data collection period. *Safety Reporting in the Study will follow the standard clinical care but will not be monitored by the study*

7.6 Data protection and patient confidentiality

Participant Confidentiality
The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

Data protection
The plan for the data management of the study is outlined below. There is not a separate data management document in use for the trial.
Source documents are where data are first recorded, and from which participants' data are obtained. These include, but are not limited to, hospital records (from which medical history and previous and concurrent medication may be summarised into the CRF), clinical and office charts, laboratory and pharmacy records, diaries, microfiches, radiographs, and correspondence.
CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). All documents will be stored safely in confidential conditions.

Data Recording and Record Keeping
The data points collected will be decided upon by the multidisciplinary steering committee, which will include primary care, secondary or tertiary care and patient reported data collection points.

The data will be collected in the *PeopleWith* platform. *PeopleWith* are the digital health technology partner working in collaboration with the Society for Endocrinology, supplying a patient/study participant facing mobile application and site-specific clinical web interface for the capture, consolidation and management of data. All data captured with the *PeopleWith* platform is timestamped and stored securely against the unique identifier of the data creator (patient/study participant or health care professional). *PeopleWith* implement strict data access policies with access recorded and logs retained for the lifetime of the study.

- Sites will have individualised log ins to the platform to input clinical patient related data.

- Sites will be required to keep a secure screening log of the patients as the data inputted into the platform will be anonymised by a patient identifier.
- Patients will input their own patient related data into the app when they see fit.
- The *PeopleWith* App user or 'Patient' acts as the owner and controller of their own data. The patient is at the centre and provides their own consent regarding sharing of their Health Data.
- *PeopleWith* acts as Data Processor as defined in the General Data Protection Regulation (GDPR).
- The *PeopleWith* Platform and App have been built from the outset using the core principle of information security; confidentiality, integrity and availability. Day to day implementation of 5 key information security protocols to mitigate risk of breach of data and system security, including remote access, password management, USB devices, acceptable use policy, routine system monitoring. Data Encryption, user access authentications, and other technical measures are in place to ensure data protection.
    - Backups occur every 24 hours and are stored in a dedicated secured, single tenant, blob storage cloud-based environment with limited access. The national clinical data collected has the potential to be layered with the patient collected data via the patient's screening number. The Society for Endocrinology will own and be the controller of the combined data in its anonymised format. *PeopleWith* will act as the data processer.
    - In the unlikely event that the PeopleWith platform can no longer be utilised for data storage, all data from the CORE Study will be moved to an alternative database held securely at the Society for Endocrinology

Data will be retained for 10 years. The study will contain identifiable data including name, date of birth and first section of postcode. The samples collected during the course of the data collection will be standard care only so there are no samples collected and stored on behalf of the study.
Patients will be asked to complete a quality of life questionnaire at every 6 months or if they have entered a new treatment or symptom.

As the patient identification key is recorded and made evident in the platform as well as recorded on the screening logs

Physically at site in accordance with ICH GCP the screening log will be kept in the Investigator Site File which will be in a locked room. Screening logs only retained for the duration of the study. Logs stored in a locked, secured location with access only permitted to designated individuals. Physical security measure implemented including; locked doors, CCTV and intruder detection dependant on the Site.

Throughout the study, various procedures ensure the confidentiality, integrity and security of data. Procedures will be implemented across sites participating in the study and through study technology partner, *PeopleWith*;

- Sites are assigned secured logins for designated individuals to the *PeopleWith* platform, restricting access to authorised personnel only.

- Role based privileges are enforced, ensuring only those who require access for their role can access the participant identification key within each site.
- Site login access logs are maintained.
- Data is encrypted at rest when stored in secured databases and in-flight when being transmitted;
    - Encryption protocols implemented throughout the *PeopleWith* platform:
        - Data in-transit: SSL with SHA-256 with RSA Encryption
        - Data at-rest: RSA 2048
        - File Storage (including backups): RSA 2048
- Designated individuals are prompted to renew their password every 90 days.
- Access is revoked upon reappointment, resignation or study completion.
- Technical safeguards implemented throughout including; automatic timeouts (10 minutes), multi-factor authentication, firewalls and intrusion detection systems.

PeopleWith acts as the technology partner contracted to the study by the Society for Endocrinology. Under GDPR, *PeopleWith* are the data processor for the study, who provide technology infrastructure to securely manage and store study data. An aggregated, anonymised dataset is made available to and is owned by the Society for Endocrinology. Additionally, *PeopleWith* support onboarding to the technology and deployment to sites, including the implementation of security measurements to protect data. The Society for Endocrinology has undertaken significant technical and information governance due-diligence with *PeopleWith* including the appointment of a Caldicot Guardian. *PeopleWith* is an ICO registered organisation with registration number: ZA745747.

Data held on the app will include:

- Participant Data:
    - Email address, gender assignment, date of birth, postcode brick (i.e. first section), ethnicity and occupation.
- Pseudonymized Data:
    - Study specific participant identification key.
- Health Data:
    - Data entered by participants, such as symptoms, medication adherence, or health outcomes.
- Survey Responses:
    - Data from questionnaires or surveys completed through the app.
- Metadata:
    - Usage data such as timestamps of logins, app interactions, and e-consent verification.
- Study Specific Data:
    - Information explicitly required for research purposes eg weight loss treatement and outcomes

Data Access

Direct access will be granted to authorised representatives from the Sponsor, regulatory authorities, and host institution to permit trial related monitoring, audits and inspections. Additional data access will be granted, in the form of an anonymised data set, to researchers who submit a data request

form. This request form and the author of the form will be scrutinised by the Steering Committee for this study and will only be granted once data compliance documents are signed by both parties. These data access requests must be for research purposes which improve service and care for the patients affected by problems with weight management.

Archiving
Archiving any documentation relating to the study will be done within 6 months of the completion of the data collection date. Archiving responsibility falls within the sites own policies on archiving. The Society for Endocrinology or the study is not responsible for the archiving of local materials.

Upon completion of the study, *PeopleWith* implements a study close out procedure to archive, consolidate and remove data and information from its systems. This procedure includes the following steps:

- Data consolidation: All study data captured via the *PeopleWith* app is consolidated and formatted into an aggregated, anonymised dataset in an agreed machine-readable format.
- Data archiving: Aggregated, anonymised data is archived, encrypted and stored in a secured cold storage server, only accessible by 1 designated member of the *PeopleWith* senior management team. Final study dataset is securely transmitted to the Society for Endocrinology. The Society for Endocrinology will keep the data for data analysis for 5 years following the closure of the study. It will be kept on a secure server which only the research team will have access to. It will be password protected and monitored by the IT department of the Society for Endocrinology.
- Study Participants:
    - Data is kept for the duration of the participants engagement with the *PeopleWith* app during the study. Upon termination of use of the *PeopleWith* app, withdrawal from the study or request under GDPR, data is deleted and removed from the platform.
    - Upon completion of the study, the participant is presented with the opportunity to continue to use a non-study configured version of the *PeopleWith* app, at which time they can agree to *PeopleWith's* Terms and Conditions of use and Data Policy. If the participant no longer agrees to use the *PeopleWith* app, their data is processed for destruction and removed from the app within 28 days.

7.7 Indemnity

Funding
Novo Nordisk, Rhythm Pharma and Boehringer Ingleheim have agreed and contracted to provide the study funding over 2 years. The funding pot will be held and managed by the Society for Endocrinology. The funding is provided to pay for the platform of the study and configuration of the application, and any additional materials the steering committee may see fit for the recruitment of patients into the study.

Insurance
NHS bodies are legally liable for the negligent acts and omissions of their employees. If participants are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the trial team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Society for Endocrinology, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

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

7.8 Access to the final study dataset

Direct access will be granted to authorised representatives from the Sponsor, regulatory authorities, and host institution to permit trial related monitoring, audits and inspections. Additional data access will be granted, in the form of an anonymised data set, to researchers who submit a data request form. This request form and the author of the form will be scrutinised by the Steering Committee for this study and will only be granted once data compliance documents are signed by both parties. These data access requests must be for research purposes which improve service and care for the patients affected by obesity. The steps involved in getting this permission are shown below

Stage 1: the lead of the application submits data request form and agreement to the Society team
Stage 2: The Society team checks the form and forwards to the Steering Group
Stage 3: The Steering Group members complete the feedback form three times per year (April, September, December)
Stage 4: Feedback form is sent back to the Society
Stage 5: The Society collates the feedback and returns to the chair of the Steering Group
Stage 6: Collated feedback sent back to the lead of the application
Stage 7: The lead of the application would formulate a response if more information required or sign the required forms for release of the data
Stage 8: The outcome of the application is circulated to the steering group
Stage 9: The data is processed at the Society for the data points requested in the application and sends to the lead of the application.

8 DISSEMINIATION POLICY

8.1 Dissemination policy

On completion of the study, the data will be analysed, and results will be disseminated via publication in clinical and physiological journals, presented at National and International conferences and in the form of feedback sheets or perhaps local articles. All participants will also be offered a debriefing meeting whereby the researcher will discuss research findings with them. Participants will not be identifiable from the results of the study.

8.2 Authorship eligibility guidelines and any intended use of professional writers

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

8.3 Publication Policy

Prior to publication of any research findings based upon Society Study data, the Investigator must comply with the following requirements (as set out in the Data Sharing Agreement):

1. All materials to be published must be submitted to the relevant Study Steering Committee for approval, no less than four weeks prior to any deadline for approval. The approval of the Study Steering Committee will be evidenced in writing.
2. Study Steering Committee members who respond to comments and proactively input to the publication should be credited with authorship, additionally SfE CORE Study Steering Committee 20XX should be credited as an author.
3. The Study itself should be credited with authorship and/or acknowledged under the format of SfE CORE Study, the institution address of Starling House, 1600 Bristol Parkway North, Bristol, BS34 8YU, and contact details of research@endocrinology.org.
4. All publications that do not include author contributions from the Study Steering Committee must include a disclaimer confirming that any views and opinions expressed in the material may not reflect the position of the Society for Endocrinology. 'The Society for Endocrinology has not reviewed this document and therefore this document may not reflect the views and opinions of the Society for Endocrinology'.

The Society for Endocrinology can be approached for endorsement via the Clinical Committee under the endorsement policy.

Disclaimer if Publication does not include authors from The Society for Endocrinology
The views and opinions expressed in this article are those of the authors and do not reflect the views of the Society for Endocrinology.

Disclaimer regarding Data Availability
The datasets generated or analysed during the current study are not available publicly but are available to access through a Data Sharing Agreement with the Society for Endocrinology.

Text to use in Methods section of abstract
Refer to the data or the Study as 'The SfE [name of Study] Study

Text to use in Methods section of full text
The 'SfE [name of study] Study is an international database of pseudonymised information on patients with [name of condition] and is approved by the Medical Research Ethics Committee in the United Kingdom as a research database of information that is collected as part of routine clinical care (Ethics Ref). The data within this study are deposited by clinicians following informed consent from patients or guardians and managed by the Society for Endocrinology.

Society logos can be made available for:
- Opening slides of original scientific communications
- Opening slide or last slide of reviews or updates
- At the top or bottom of physical or e-posters

Please contact the Society at research@endocrinology.org to make requests for logos or to check any references to the study within the body of your publication.

9 REFERENCES

1. http://www.oecd.org/newsroom/healthier-lifestyles-and-better-health-policies-drive-life-expectancy-gains.htm
2. Moody A (2016) Health Survey for England 2015 Adult overweight and obesity, http://www.content.digital.nhs.uk/catalogue/PUB22610/HSE2015-Adult-obe.pdf (accessed 8 May 2018).
3. Welbourn R, Small P, Finlay I, et al., on behalf of The United Kingdom National Bariatric Surgery Registry (NBSR) (2014) Second Registry Report 2014, http://www.bomss.org.uk/wp-content/uploads/2014/04/Extract_from_the_NBSR_2014_Report.pdf
4. https://www.omc-uk.org/directory?display_name=&tier_1=1

10. APPENDICIES

10.1 Appendix 1- Required documentation

Local Information Packs will include

Protocol, Patient Information Sheet, Patient Flyer, E-Consent Information, Data Access Policy, IRAS form, SoECAT, CV of Chief Investigiator, Data Dictionary.

Local Sites will be asked to provide

Delegation log, CV and GCP of site staff, confirmation of capacity and capability

10.2 Appendix 2 – Schedule of Procedures

Timepoint	Event
Baseline	Informed Consent, Clinical Data Collected, Questionnaires (EQ5D and BODYQ) via Patient app, clinical data collected
Every 12 months until exit of clinic or study ends	Clinical Data Collected, Questionnaires (EQ5D and BODYQ) via Patient app
Triggered patient data collection	Upon notification every 3 months, patients will be invited to update treatments and symtoims. If there are new additions then a triggered EQ5D and BODYQ will be asked of the patient via the patient app.

10.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made