OK:DIABETES

Managing with Learning Disability and Diabetes

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Other collaborators are detailed in Appendix 2: Project Management Group.

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1 STUDY SUMMARY

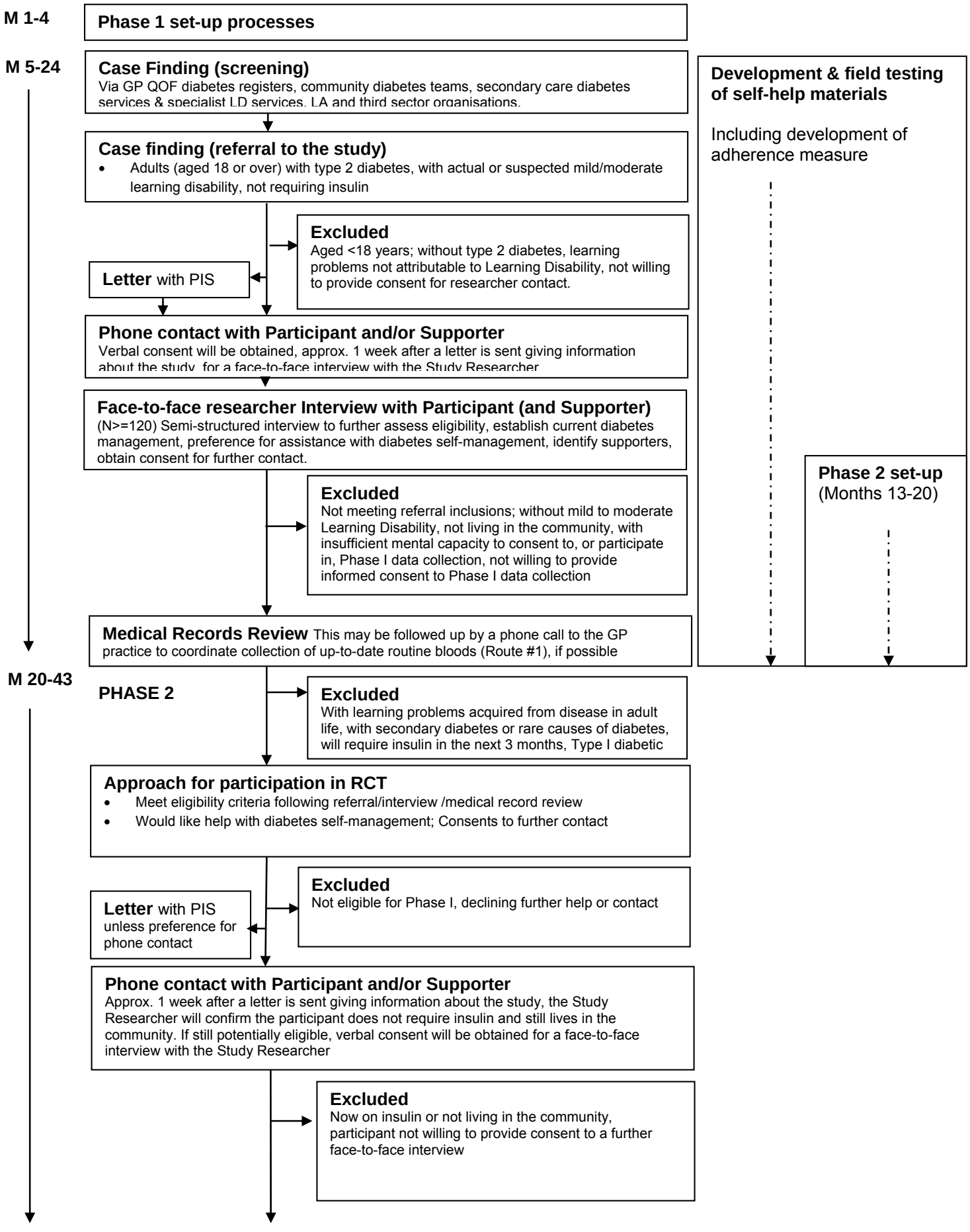
This research involves two phases. In Phase I we will identify and characterise potential participants and develop a self-management manual and adherence measure. Phase II will be a feasibility Randomised Controlled Trial (RCT).

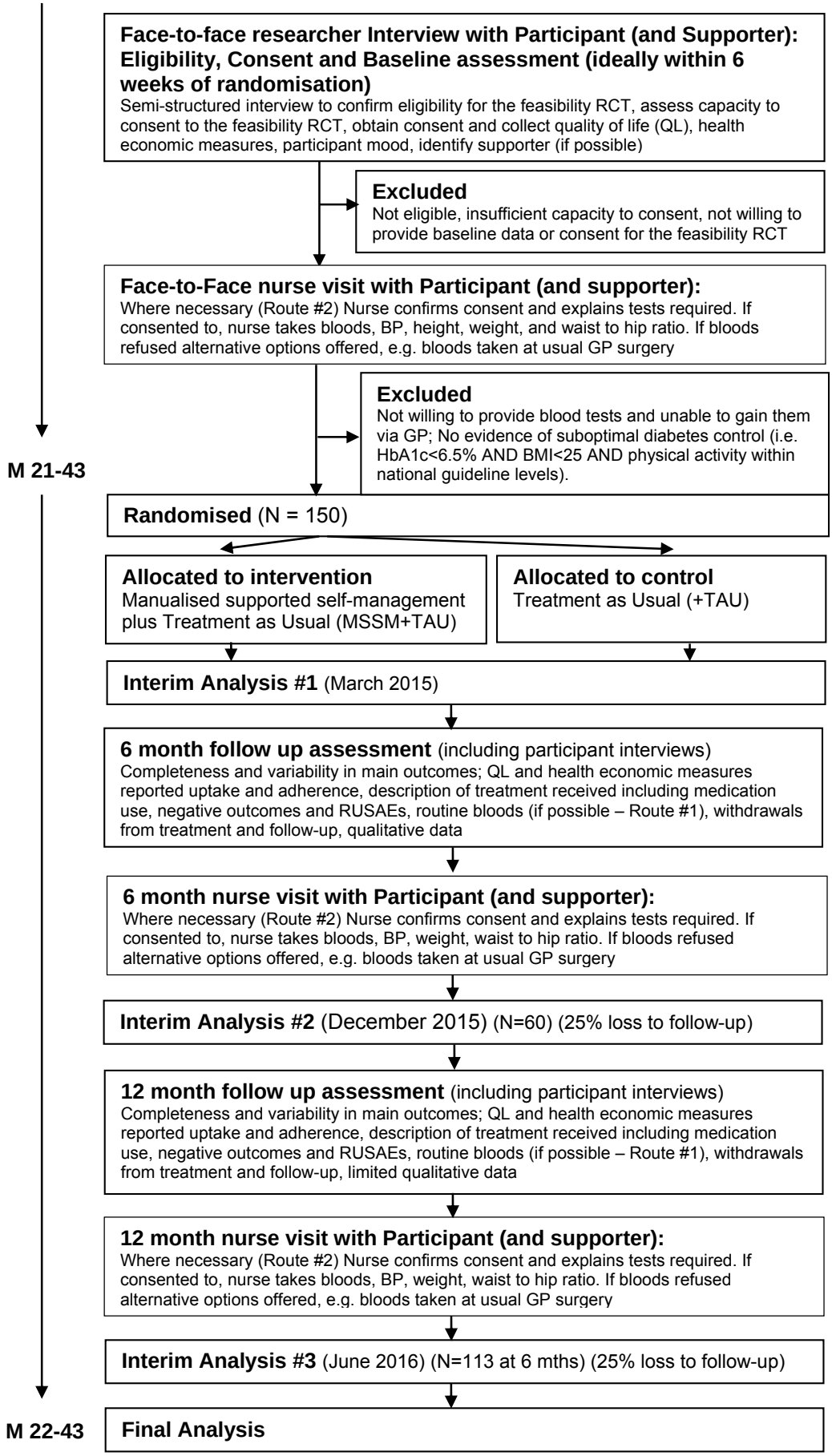
Phase I
Objectives: 1) To develop and evaluate a simple case-finding method; 2) To develop a manualised intervention to aid supported self-management of diabetes; 3) To assess the feasibility of delivering the intervention; 4) To develop a simple measure of adherence to the manualised intervention; 5) To develop procedures for determining and recording capacity and obtaining consent.
Design: Prospective case-finding survey.
Setting: Three cities in West Yorkshire: Bradford, Leeds and Wakefield.
Target population: Adults 18+years, with type 2 diabetes, not using insulin, with mild to moderate Learning Disability (LD) attributable to primary or secondary intellectual impairment, living in the community without neurological problems acquired from disease in adult life, and who have sufficient mental capacity to consent to the research.
Technologies: (1) A simple checklist will be developed to enable staff working in primary care (and in a range of other NHS and non-NHS settings) to identify potential participants as they undertake Quality and Outcomes Framework (QoF) diabetes checks; (2) Self-management materials will be developed - from existing literatures in Learning Disability and diabetes and chronic disease self-management, and from content of related care pathways such as that for obesity in Learning Disability. The manualised self-management intervention will have selectable components to allow variable involvement with a supporter. It will have a component for the participant, for a supporter, and for shared activities; (3) An adherence measure will be developed.
Procedures: All potential participants will be interviewed to [a] identify those who meet entry criteria, [b] establish current diabetes management and current physical health state from QoF measures, [c] identify supporters and their role in diabetes management, [d] elicit preference for further assistance with diabetes self-management and consent to further researcher contact.
Outcomes: Robust estimate of eligibility and characterisation of eligible population; development of a manual and an adherence measure.
Sample size: Target originally 350; reduced to a minimum of 120 for the feasibility RCT and 200 for proof of concept (PoC).

Phase II Objectives: 1) To estimate recruitment and retention rates; 2) To assess the feasibility of collecting a range of outcomes including those for a health economics evaluation and to measure variability; 3) To develop a checklist of potential negative outcomes and a related process for their collection, with a preliminary assessment of the acceptability of the intervention; 4) To test the performance of data collection forms and associated processes; 5) To assess the feasibility of delivering the intervention; 6) To test the feasibility of using a standardised adherence measure to assess delivery and use of self-management techniques; 7) To provide a detailed description of what treatment is delivered to each arm; 8) To assess proof of concept (PoC) in relation to potential efficacy of the intervention
Design: Individually-randomised feasibility RCT of manualised supported self-management plus treatment as usual (MSSM+TAU) versus treatment as usual (TAU).
Target population: Participants identified in Phase I still not using insulin, still living in the community, with evidence of suboptimal diabetes control (i.e. HbA1c > 6.5% (equivalent to 47.5 mmol/mol), or BMI > 25, or self-reported physical activity below national guideline levels) who have sufficient mental capacity to consent to the trial. Participants without supporters will be included; those who have a supporter who declines participation will also be included.
Technology: Manualised supported self-management of diabetes (MSSM), the basic elements of which will be standardised but flexibly delivered, will be provided to the intervention arm. A standard leaflet will be provided to the control arm. TAU will be provided in both arms according to the usual

practices and local service policy.
Data Collected (6 and 12 months): Recruitment and retention rates; Variability of and % abnormal (on standard criteria) for HbA1c, BMI, BP, waist to hip ratio, Vascular risk markers (fasting and non-fasting triglycerides, fasting glucose, cholesterol, Urea and Electrolytes or serum creatinine), Microvascular risk marker (micro-albuminuria), Marker of microvascular disease (retinopathy), participant mood; Data quality (including % availability of QOF data from the last 15 months); description of, uptake and adherence to MSSM and SL; description and comparison of TAU across arms; medication use; negative outcomes; potential contamination within households; health economic data (health-related quality of life (QL): EQ5D, NHS and supporter costs); qualitative data (positive and negative experiences of implementing self-management, further detail regarding TAU); withdrawals from treatment or follow-up, RUSAEs, PoC (HbA1c at 6 months).
Sample size: Minimum of 80 for feasibility, and 150 for PoC

1.1 FLOW DIAGRAM




Face-to-face researcher Interview with Participant (and Supporter): Eligibility, Consent and Baseline assessment (ideally within 6 weeks of randomisation)
Semi-structured interview to confirm eligibility for the feasibility RCT, assess capacity to consent to the feasibility RCT, obtain consent and collect quality of life (QL), health economic measures, participant mood, identify supporter (if possible)
Excluded
Not eligible, insufficient capacity to consent, not willing to provide baseline data or consent for the feasibility RCT
Face-to-Face nurse visit with Participant (and supporter):
Where necessary (Route #2) Nurse confirms consent and explains tests required. If consented to, nurse takes bloods, BP, height, weight, and waist to hip ratio. If bloods refused alternative options offered, e.g. bloods taken at usual GP surgery
Excluded
Not willing to provide blood tests and unable to gain them via GP; No evidence of suboptimal diabetes control (i.e. HbA1c<6.5% AND BMI<25 AND physical activity within national guideline levels).
M 21-43
Randomised (N = 150)
Allocated to intervention
Manualised supported self-management plus Treatment as Usual (MSSM+TAU)
Allocated to control
Treatment as Usual (+TAU)
Interim Analysis #1 (March 2015)
6 month follow up assessment (including participant interviews)
Completeness and variability in main outcomes; QL and health economic measures reported uptake and adherence, description of treatment received including medication use, negative outcomes and RUSAEs, routine bloods (if possible – Route #1), withdrawals from treatment and follow-up, qualitative data
6 month nurse visit with Participant (and supporter):
Where necessary (Route #2) Nurse confirms consent and explains tests required. If consented to, nurse takes bloods, BP, weight, waist to hip ratio. If bloods refused alternative options offered, e.g. bloods taken at usual GP surgery
Interim Analysis #2 (December 2015) (N=60) (25% loss to follow-up)
12 month follow up assessment (including participant interviews)
Completeness and variability in main outcomes; QL and health economic measures reported uptake and adherence, description of treatment received including medication use, negative outcomes and RUSAEs, routine bloods (if possible – Route #1), withdrawals from treatment and follow-up, limited qualitative data
12 month nurse visit with Participant (and supporter):
Where necessary (Route #2) Nurse confirms consent and explains tests required. If consented to, nurse takes bloods, BP, weight, waist to hip ratio. If bloods refused alternative options offered, e.g. bloods taken at usual GP surgery
Interim Analysis #3 (June 2016) (N=113 at 6 mths) (25% loss to follow-up)
M 22-43
Final Analysis

2 BACKGROUND

The prevalence of type 2 diabetes has increased sharply in recent years in line with increasing obesity in the general population. Prevalence across the population varies markedly by ethnicity and social factors including deprivation. Case finding for service planning and for research is greatly facilitated in the UK by the fact that general practitioners are required to maintain a register of all patients with diabetes, and are remunerated through the Quality Outcomes Framework (QOF) for undertaking various health assessments on an annual cycle [1]. For example in Leeds (Pop ~725k) there are >27000 on the QOF diabetes register and in Bradford (Pop ~520k) there are 26500 on the QOF diabetes register. This gives population prevalence rates that are typical of published figures from elsewhere of 4% and 5% respectively, the difference largely accounted for by the fact that a third of the adult population of Bradford is of South Asian origin, predominantly Pakistani.

Learning Disability is less straightforward to define and identify, especially at the milder end of the spectrum. It can be defined statistically based on test scores, which typically show a negatively-skewed distribution, and in those terms, it is often said that 2% of the general population will have some degree of Learning Disability [2-4]. However, the picture becomes more complex when an element of functional impairment in real-world activities is built into the definition. Part of the problem is that any functional deficit may not be entirely attributable to intellectual impairment but to (for example) emotional or social problems or missed schooling. Conversely, an adult with intellectual impairment may not come to the attention of statutory or non-statutory agencies if he or she is functioning independently or is well supported by family or some other informal carer.

The functional approach to definition and terminology is now widespread [5, 6] and accounts for a shift in practice so that in routine discourse Learning Disability (referring to an intellectual impairment) and Learning Difficulty (referring to a functional state) are often used interchangeably. However, a problem arises as in many cases the term ‘Learning Difficulty’ is used to refer to a specific deficit such as dyslexia, even when it is not associated with more general intellectual impairment. Practice varies in this respect; for the purposes of this study we use the term Learning Disability (LD) to encompass all types of intellectual deficit that lead to problems with self-management.

A corollary of the definitional problem is one of case finding. It is well recognized that a minority – probably a quarter or less of the adult population with Learning Disability – is known to health or social services [7]. Thus although there is an estimated 14 000 people in Leeds with Learning Disability only 3300 are in receipt of paid support (personal communication, Joint Commissioning Support Manager, Leeds City Council). This is true even for those people who have both a Learning Disability and a physical health problem. For example in Leeds only 75/27000 (0.3%) and in Bradford only 64/26500 (0.25%) of those on QOF diabetes registers are also on GP learning disability registers. Assuming 2% adults have Learning Disability, the respective numbers should be nearer 540 and 530. This is an unfortunate state of affairs because it is apparent that adults with Learning Disability have high rates of physical illness, and a recent report highlighted their poor levels of healthcare [3, 8].

One further cause of complexity is that many adults with Learning Disability do not live entirely independently even when they can be defined as living in the community – that is, not living in hospital or residential care. Family members and other informal or formal carers often provide support in the form of help with shopping, cooking, monitoring and prompting about medication and so on. Arrangements here are diverse:- some adults with Learning Disability have never left the parental home; some live with a sibling or other relative, some live alone or in shared accommodation with non-resident support or peer support from those with whom they share; some are married or cohabiting with somebody who may or may not themselves have a Learning Disability. This means that self-management needs to be negotiated not just with the person with

diabetes but with their supporter, and that considerable flexibility will be needed in negotiating and implementing an intervention.

There are a number of possible explanations for high rates of poorly-controlled type 2 diabetes in adults with Learning Disability – high prevalences of obesity [9] and poor dietary habits; prescription medications that increase risk; poor self-management skills [10]. An additional complication is that some people with Learning Disability – mainly those with moderate or severe disability - have a very narrow dietary range with preoccupation with eating or avoiding certain foods, a characteristic that is sometimes linked to other autistic behaviours.

Supported self-help or self-management with health problems is now reasonably well established, although the intensity with which it is delivered and its content have varied considerably between studies [11]. In relation to intensity, the main variation is in amount of contact with the supporter/ therapist – which ranges from regular face-to-face meetings to limited telephone contact. As regards content, all programmes contain an educational and an instructional component, the variation residing mainly in the degree of formal techniques for supporting behaviour change and the degree to which they are theory-based. Deciding on the components of an intervention is likely to be derived from the existing self-management programmes for diabetes in adults without Learning Disability with a focus on behaviours likely to promote healthy eating, physical activity and medication adherence. However, the usual pattern for support is that a professional (or trained peer) acts as a "therapist" to help and encourage the nominated patient in using the self-management materials. That may be the model in some cases in this project, but we also expect much of the work to be undertaken through the involvement of informal supporters who are already providing input and whom we would not wish to by-pass or displace.

The relevant self-management material is largely educational and didactic with little or nothing that facilitates behaviour change – advice about self-monitoring for example. There is also little on the interaction between the person with diabetes and others supporting their care. Another important modification will be in the format of materials, which in traditional self-management are largely written – either in paper form or online. For our purposes, we will need more visual materials to circumvent literacy problems, and it is challenging to make those self-explanatory and to decide the best mix of formats. We do not know for example what proportion of our target population has access to, or knows how to use, a DVD player or the internet.

For these reasons, there is considerable preparatory work to do before a feasibility RCT can be undertaken, as outlined in Phase I of our study. The aim of this work is to assess the feasibility of conducting a definitive trial of manualised supported self-management plus treatment as usual versus treatment as usual in adults with Type 2 diabetes and LD.

The funders have asked us to consider increasing the sample size for the feasibility RCT from 80 patients to 150 to allow us to also evaluate proof of concept in terms of a reduction in HbA1c. If the proof of concept analysis provides enough evidence of efficacy to proceed to a definitive trial then the feasibility RCT would form an internal pilot for the main RCT.

3 STUDY ORGANISATIONAL STRUCTURE

For the purposes of both phase I and II, the study will be organised and managed as follows:

3.1 RESPONSIBILITIES

Sponsor

The Sponsor takes responsibility for confirming there are proper arrangements to initiate, manage, monitor and finance the study. These responsibilities are delegated to the Clinical Trials Research Unit (CTRU) and Leeds Institute of Health Sciences (LIHS) as detailed in the trial contract.

Chief Investigator
As defined by the NHS Research Governance Framework, the Chief Investigator is responsible for the design, management and reporting of the study.

Clinical Trials Research Unit (CTRU)
The CTRU will have responsibility for data management and statistical aspects relating to the conduct of the study and will work in accordance with relevant CTRU SOPs and the NHS Research Governance Framework (RGF). CTRU responsibilities include registration and randomisation design and service, database development and provision, input to protocol development, input to CRF design, trial design, data monitoring and management, safety reporting and statistical analysis. In addition the CTRU will support the project manager at LIHS by providing an interface role – linking project management and data management across organisations. They will also be responsible for leading a literature review of measures of adherence and contributing to the development of a simple adherence tool.

Health Economists
The Academic Unit of Health Economics at the University of Leeds will be responsible for a literature review, the selection and design of the resource use questionnaire, the development of the Health Economics sections of the protocol, for carrying out associated analyses and for presenting these results.

Study Researchers
Study Researchers will have responsibility for participant and supporter contact, consent, assessment/interviewing and follow-up of participants identified for inclusion in the study, in accordance with procedures outlined in the protocol. They will also be responsible for feasibility work.

Research Nurse
The research nurse will be a qualified nurse trained and experienced in venesection/venipuncture and employed to deliver the intervention. They will be responsible for attending training sessions, ensuring that the participant continues to give consent, delivering the intervention according to protocol, taking physical measures including blood samples and collecting adherence measures as agreed in Phase I. The research nurse will have responsibility for the taking and storage of blood according to Leeds Teaching Hospital policies. They will be trained by service user groups and PPI representatives in the best way to communicate with people with learning disabilities, how to explain blood tests and physical measures and the best ways to reassure their patients.

3.2 OPERATIONAL STRUCTURE

A Project Working Group (PWG), including key individuals from LIHS and CTRU will meet on a monthly basis to manage the day to day running of the project. A Project Management Group (PMG), involving LIHS, CTRU and Co-applicant members will meet on a 3 monthly basis to oversee the running of the trial. A Trial Steering Committee (TSC) with a safety monitoring function will meet at least 6 monthly to provide independent review. The trial will be conducted in accordance with the Standard Operating Procedures of the CTRU, study-specific guidance produced by LIHS and CTRU, MRC GCP, the Research Governance Framework, and in line with appropriate elements of the Mental Capacity Act. There will be clear lines of responsibility for project management, timescale monitoring, consent & recruitment monitoring, compliance, analysis, ethical issues, and participant safety. A trial database will ensure data security and facilitate data quality, follow-up, and trial monitoring.

Project Management Group (PMG)

The PMG, chaired by the Chief Investigator, will be assigned responsibility for the clinical set-up, clinician training, on-going management and promotion of the study, and for the interpretation of results**.** Specifically the PMG will be responsible for (i) protocol completion, (ii) CRF development, (iii) obtaining approval from the main REC and supporting applications for Site Specific Assessments (SSA), (iv) completing cost estimates and project initiation, (vi) nominating members and facilitating the TSC, (vii) reporting of related and unexpected serious adverse events, (vii) monitoring of screening, recruitment, consent, treatment and follow-up procedures, safety, data quality and compliance, (viii) interpretation of results and contribution to publications, (ix) auditing consent procedures, data collection, trial end-point validation and database development. The PMG will operate in line with the CTRU's Committee Terms of Reference for TMGs as amended and agreed by PMG members at their first meeting.

Trial Steering Committee (TSC)

The Trial Steering Committee (TSC) (Appendix 3) will provide overall supervision of the study, in particular study progress, adherence to protocol, patient safety and consideration of new information. It will include an Independent Chair and not less than two other independent members, including an experienced Trial Statistician and consumer representative. The Chief Investigator and other members of the PMG will attend the TSC meetings and present and report progress. A subcommittee of the TSC will be convened if necessary to monitor safety data. The TSC will operate in line with the CTRU's Committee Terms of Reference as amended and agreed by TSC members at their first meeting.

Data Monitoring Committee (DMEC)

If we randomise to target and receive funding to follow-up sufficient participants, the TSC will set-up a separate independent Data Monitoring Committee (DMEC) to consider results of planned interim analyses and to make recommendations to the TSC about whether to proceed. It will include an Independent Chair and not less than two other independent members, including an experienced Trial Statistician. The Trial and Supervising Statisticians will attend meetings to present interim analyses, with the rest of the team remaining blind. The DMEC will operate in line with the CTRU's Committee Terms of Reference as amended and agreed by DMEC members at their first meeting.

4 PHASE I – CASE FINDING STUDY

4.1 OBJECTIVES

1. To develop and evaluate a simple case-finding method to identify participants who have both mild/moderate Learning Disability and Type 2 diabetes who are not taking insulin and who might be suitable for supported self-management. Follow up interviews will confirm eligibility and identify key supporters.

2. To develop a manualised intervention to aid supported self-management of diabetes; the manual will be designed to balance the needs for a standardised approach against the need to take into account variability in the eligible population - in personal function and in availability of a supporter involved in diabetes management.

3. To assess the feasibility of delivering the intervention via qualitative interviews.

4. To develop a simple measure of adherence to the manualised intervention

5. To develop procedures for determining and recording capacity and obtaining consent.

4.2 DESIGN

A three-site (Leeds, Bradford, Wakefield) prospective case-finding survey involving a minimum of 120 participants for the feasibility RCT and 200 for the PoC analysis assessed as having diabetes and learning disabilities. All consecutive patients on registers in primary and secondary care and in third sector organisations will be screened to identify potential participants. A proportion of these, or other PPI contributors will be involved in developing the self-management materials. All data, qualitative and quantitative, will be collected from medical notes, by a research nurse or by a Study Researcher at interview.

Although the intention is to recruit people with Learning Disability and Type 2 diabetes even if they live independently and have no informal carer/supporter, it is expected that the majority of participants will have one. Supporters will be defined as any adult who is nominated by themselves, by the person with diabetes, or by a professional who knows that person, as providing practical help and support in day-to-day living of a sort relevant to their diabetes management (e.g. shopping, cooking, prompts about tablets). The supporter does not need to be co-resident but must provide more than emotional support. The supporter may also have a Learning Disability and this would not exclude them, providing they were also able to give informed consent. If more than one supporter is identified, the principal or main supporter will be identified to work with, as nominated by the participant. Otherwise, more than one supporter will be included if it is practical to do so.

4.3 ELIGIBILITY

4.3.1 INCLUSION CRITERIA

Participants meeting the following criteria are eligible providing they don't meet any of the exclusion criteria:

- Aged 18 years or over
- Suffering from Type 2 diabetes which is diet-controlled or treated with hypoglycemic agents other than insulin
- With a mild to moderate Learning Disability, defined by functional deficits (in daily activities, educational and social attainment and support needs, day-to-day cognitive functions of memory and knowledge) attributable to primary or secondary (acquired) cognitive impairment. Where cases are borderline or complex, the decision may be made through discussion within the team including the LD Consultant Living in the community (not in a hospital setting)

4.3.2 EXCLUSION CRITERIA

Participants meeting any of the following criteria will not be eligible:

- Insufficient mental capacity to consent or to participate in the research, as assessed by the Study Researcher following guidelines using the Mental Capacity Act (2005) with people with learning disabilities (http://www.scie.org.uk/publications/mca/files/bild-mca.pdf). Study Researchers will be trained by LD consultant to undertake this assessment.
- Problems acquired from disease in adult life, defined as 16 years or over, such as learning difficulty due to adult-onset dementia or stroke
- Secondary diabetes (such as steroids, pancreatitis, endocrine disorders etc.) and rare causes of diabetes (such as MODY: maturity onset diabetes of the young)
- Requires insulin in the next 3 months

Eligibility waivers to inclusion and exclusion criteria are not permitted.

Eligibility will be assessed in stages (i.e. referral, phone contact, face-to-face interview, medical records review). The criteria may therefore be assessed at different levels in different contexts – this is particularly the case with Learning Disability, where initially at referral the criterion "suspected Learning Disability" will hold but after the face-to-face interview and subsequent discussion within the team and with the LD Consultant for complex cases it will be "probable mild to moderate Learning Disability".

4.4 RECRUITMENT

In Leeds alone there are an estimated 14,000 people with Learning Disability of whom 700 (5%) have type 2 diabetes, with type 2 diabetes being more common here than in the general population. Across the three sites, there should be approximately 1400 people in the target population. We initially assumed 50% GP involvement and 50% eligible adults, making it possible to identify approximately 350 people or one-quarter of the total population through QOF screening, supplemented by our other case finding methods. Minority ethnic groups, especially of South Asian origin, are well represented in the cities. A typical practice list will recruit only 1-2 participants and thus we do not expect cross-contamination to be an issue.

During the course of Phase I, our anonymised search of the registers found 319 potentially eligible participants across Leeds, Bradford and Wakefield. We had not expected to find that approximately 20% of people with Learning Disability with type 2 diabetes are prescribed insulin. Most referrals therefore needed to come from the population with LD who were not labelled as such or entered onto a GP learning disability register. We overestimated the ability of GPs to identify and refer such cases and as a consequence a more realistic target has been agreed by the TSC. We anticipate that 200 will be sufficient to achieve the 150 recruits needed for the PoC analysis and that 120 will be sufficient to achieve the 80 recruits needed for the feasibility RCT.

Services for type 2 diabetes vary considerably across the NHS and in our three participating cities. In Leeds most cases are managed exclusively in primary care with referral to secondary services only for specific problems. In Bradford there is a tiered system in evolution: almost half the practices provide level 2 (including insulin transfer) and several practices participate in collaborative care of complex cases. In Wakefield there are specialist teams across primary and secondary care, and all people with diabetes have shared management plans. There is also a wide range of services for people with Learning Disability in the social care and third sectors. This diversity will increase the generalisability of our findings. In practice, it will mean that flexibility is needed with respect to recruitment strategies in each location.

Research sites will be required to have obtained local management approvals prior to the start of recruitment. Recruitment will continue for a period of 27 months even if the target recruitment is then exceeded. Recruitment to Phase I will continue into Phase II, with a fixed end date of 31st August 2015 marking the end of the recruitment period to Phase II.

4.4.1 IDENTIFICATION AND REFERRAL PROCESS

Staff working in a range of settings will identify potential participants for referral. This will include:

- General practitioners
- Primary care staff undertaking QOF diabetes checks and QOF learning disability checks
- Primary care staff in community diabetes teams
- Secondary care staff in diabetes services
- Secondary care staff in specialist learning disability services
- Local Authority services for learning disability
- Third Sector organisations

A simple referral checklist will be used, based on the following criteria:

- Aged 18 or over
- Known to have type 2 diabetes and not requiring insulin therapy
- Problems attributable to Learning Disability (based on a list of prompts)

Once identified, the referrer will obtain and document consent from the potential participant to pass on their name, address and telephone number (or that of a supporter if they prefer) to the research team. A letter and participant information sheet will then be sent from the research team to the potential participant (and supporter if identified) giving information about the study. This will be followed up about a week later by a telephone call giving the potential participant (or supporter), and the supporter where applicable, an opportunity to discuss the study further. During the phone call, verbal consent will be obtained for a face-to-face interview with the Study Researcher.

4.4.2 SCREENING

The Study Researcher will collate the Study Referral Forms together on a weekly basis and pass them to CTRU to enter onto an anonymous Screening Database at CTRU. The data will include:

- Screening ID
- Age
- Gender
- Ethnicity
- Preferred method of contact
- Potential eligibility
- Reasons for ineligibility (where applicable)
- GP practice or other service referred from

Documented reasons for ineligibility, declining contact or non-registration will be closely monitored by the Study Researcher as part of a regular review of recruitment process.

4.4.3 FACE-TO-FACE INTERVIEW

The face-to-face interview will take place either in clinic, at home or in a location of the participant's choosing and will assess all referrals using a standardised semi-structured interview format designed for the study, to:-

- Discuss the patient information and obtain written or verbal (where necessary) informed consent for this part of the study from potential participants and their supporters. We will provide training for the research interviewer to assess mental capacity to make this judgment, and guidance on how to appropriately communicate ineligibility to individuals and their supporters. This training will be documented and will take place prior to authorisation to approach participants.
- Obtain consent to review healthcare records to assess current physical health state from QOF measures (HbA1c, BP, BMI, Q Risk, thyroid function, total cholesterol, triglycerides, urinary albumin: creatin ratio).
- Establish current diabetes management including diet and physical activity levels using content derived from standardised measures such as the summary of diabetes self-care activities measure [12] adapted for this group.
- Elicit preferences for further assistance and consent to re-contact.
- Identify the role of supporters in diabetes management, nominating a stable supporter where possible to be involved in the feasibility study (Phase II) as applicable.

In relation to entry, we will use an inclusive functional approach to identifying Learning Disability based upon a standardised discussion with participants around a modified version of the framework developed by RCN (http://www.rcn.org.uk/__data/assets/pdf_file/0006/78765/003184.pdf)

Activities
Can/do they:

✦ read

✦ write

✦ manage money

✦ look after their personal care

✦ tell the time

✦ cook

✦ have difficulty in communicating with other people?

Remember
Can they remember:

✦ significant things about themselves (e.g. birthday)

✦ significant things about their environment (e.g. where they live)

✦ when to do things (get up, what time dinner is)

✦ what you have said?

Life experience
Have/do they:

✦ attended a special school, or statement of special educational need,

✦ attend a day centre

✦ live outside a hospital or a LD residential service

✦ have people who support them e.g. care manager, advocate, or informal supporter?

The Study Researcher will explore these areas. Agreement about the presence of Learning Disability will be reached firstly by the referrer and secondly by discussion of cases in the research team. Careful note will be made of the grounds for inclusion or exclusion in each case. The researchers will use journaling techniques to outline their decision making regarding capacity decisions and all cases where there is any doubt about capacity or diagnosis will be discussed with the research team. We recognize that the main challenge will be to identify people with mild Learning Disability who are not already so-designated by themselves or others and yet who might benefit from the programme. There is currently no standardised definition or case finding approach in routine use, upon which we can rely. By the means outlined above, we aim to use a case-finding method with real utility in routine practice, whilst achieving sufficient reliability that others can replicate our approach. The local site will provide an interpreter if one or both of participant/supporter is not fluent in English. In the rare event that no suitable interpreter is available, this will act as an exclusion criterion.

4.4.4 INFORMED CONSENT

We will include in Phase I only those with the capacity to consent to the research. Potential participants will have already received a copy of the relevant participant information sheet when they discuss the study with the Study Researcher over the phone. They will receive, over the phone, an invitation to meet the Researcher for the face-to-face interview, so will have had at least 24 hours to consider participation prior to the first telephone call and subsequent face-to-face meeting with the Study Researcher. They will have had the opportunity to discuss the study with their family and healthcare professionals before they are asked whether they would be willing to take part.

During the telephone call and at the face-to-face meeting with the Study Researcher an explanation of the study will be provided and potential participants will be given the opportunity to ask questions. Information-giving will include appropriately tailored information about the rationale, design and personal implications of this element of the study. The Study Researcher will receive advice and support in this from our 3rd sector partners, and will be familiar with standard guidance on the topic [13]. For those participants interested in being involved in further research, the Study Researcher will ensure that they are aware that a second information sheet will tell them more about Phase II and a second consent process will take place along with a final eligibility check and that there is a chance that they could be found to be ineligible for the feasibility RCT at that stage. We will meet out of pocket and travel expenses of potential participants, ensuring that we handle cash transfers suitably, paying reasonable travel expenses. We will not offer either cash or non-cash incentives to participation.

The right of the participant to refuse consent without giving reasons will be respected. If the participant agrees to participate then informed consent will be obtained. The original consent forms will be held centrally at the CTRU. The Study Researcher will make copies of the original consent form for themselves. The Study Researcher will send the participant a certificate of participation and

their GP a letter confirming consent. A copy of the consent form will be available to the participant and their GP on request. The GP may pass this information to the team in charge of the person's diabetes care.

The Chief Investigator retains overall responsibility for the informed consent of participants across the sites and must ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained and competent to participate according to the ethically approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki 1996. It is expected that such responsibility will be delegated to the Study Researchers. The Chief Investigator also takes responsibility for ensuring that all vulnerable participants are protected and participate voluntarily in an environment free from coercion or undue influence.

4.4.5 REGISTRATION

Consent must be obtained prior to registration. All referrals that provide documented consent at Phase I will be registered, using a secure, automated 24-hour telephone registration service based at the CTRU, University of Leeds. Authorisation and PIN codes will be required to access the registration system and will be provided by the CTRU when all relevant study approvals are in place.

The following details will be required at registration:
- Name of Researcher
- Name of recruiting site
- Participant details: initials, date of birth
- Confirmation of eligibility*
- Consent for referral to Phase I

*Eligibility is ascertained according to the information available to the researcher at the time of registration. Following registration, the Study Researcher will follow up with the participant's GP to determine final eligibility for Phase I via their medical notes.

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Participants in Phase I will not be provided with a Trial ID from the registration system; they will retain the same ID allocated at referral.

4.5 DEVELOPING SELF-MANAGEMENT MATERIALS AND AN ADHERENCE MEASURE

We will field test the materials and adherence measure with learning disability service user groups from our PPI collaborators Sources for the self-management materials will include:

- Existing literatures in Learning Disability and diabetes and in chronic disease self-management, especially related to key areas such as diet, physical activity and medication adherence.
- Material from related care pathways that we have identified from local service providers, such as that for obesity in learning disability.
- A range of already published materials for service users, for example Diabetes-UK produces a DVD [14], an illustrated book [15] is published by Books Beyond Words, and a further booklet is published by the Learning Disabilities Federation [16].

The content will cover obvious topic areas like shopping, preparing food, planning physical activity, remembering tablets, avoiding unhealthy behaviours like smoking or drinking too much alcohol. The

materials will have selectable components to allow variable involvement with a supporter who may be currently shopping, cooking or supervising meals. They will have a component for the participant, for a supporter, and for shared activities. We will include both educational material and resources to encourage the use of simple behaviour-change techniques like self-monitoring.

The format of the materials will be mainly paper-based but we will explore possibilities for audio-visual materials. We will review the suitability of existing materials and choose the most appropriate formats. If existing audio-visual materials are not considered suitable, for example, by service users working with the third sector groups, we will consider commissioning a simple animation DVD from a local organisation.

We will develop these materials in collaboration with "Easy on the i" in a series of meetings and workshops, field-testing emerging components with consenting participants identified during case-finding. Research nurses will be involved at this stage to ensure feasibility, since they will form the professional support element, as explained below.

We will develop an adherence measure as there is not a suitable measure of adherence to self-management regimes in the literature. We will develop a simple measure designed to determine whether the participants are given the materials and are using the materials – so testing knowledge of the materials contents and use of materials, collated at the end of each participants' time in Phase II.

4.6 WITHDRAWAL

Data collected prior to withdrawal of consent will be included in the analysis, unless the participant explicitly withdraws consent for their data to be used.

4.7 DATA COLLECTION / ASSESSMENTS

The following will be collected during Phase I:

Table 1: Phase I Summary of Assessments

Assessment (including who is involved)	Referral	Phone	Face-to-face Interview	Medical Notes
Screening				
Demographic data including (i) age, (ii) gender, (iii) ethnicity	X			
Preferred method of contact	X			
Eligibility and consent				
Eligibility (assessed by Referrer, Study Researcher; confirmed by Clinician), including reason for exclusion	X	X	X	X
Documented consent to contact (Ref, P*)	X			
Verbal consent to interview (P, S, R)		X		
Mental capacity to consent to Phase I (P, R)			X	
Written consent to Phase I (P, S, R), including access to GP notes for QOF			X	
Documented consent to re-contact (P, S, R)			X	
Baseline data (P, S, R)				
Presence and role of a supporter		X	X	
Demographic data including (i) Household composition, (ii) type of housing, (iii) marital status, (iv) nature of support, (v) employment status, (vi) first language			X	
Current physical health state from QOF measures (HbA1c, BP, BMI, Q Risk)				X
Prescribed diabetes regime (medication)			X	X
Preferences for further assistance (P, S, R)			X	

* Ref = Referrer, P = Participant, S = Supporter, R = Researcher

The CTRU will maintain a file of essential documentation (Trial Master File) and keep the original of all completed CRFs (copies will be retained at LIHS). The Study Researchers undertake to adopt all reasonable measures to record data in accordance with the protocol. Under practical working conditions, however, some minor variations may occur due to circumstances beyond their control. All such deviations will be documented on the study records, along with the reason for their occurrence; where appropriate, deviations will be handled in accordance with the Statistical Analysis Plan and may be detailed in the published report.

4.8 HEALTH ECONOMICS

We will develop data collection forms for use in a definitive RCT to assess the cost effectiveness of manualised supported self-management. These will be field tested with service users from our PPI collaborators alongside the adherence measure. Self-management interventions are likely to have a wide range of outcomes given that the intervention is designed to both improve health and empower the patients. It is generally argued that a societal perspective is adopted within economic evaluation of self-management interventions given that patients costs are likely to be more important than with more conventional interventions [17]. Thus, drawing on existing literature in learning disability and diabetes, the data collection forms will identify patient resource use from the perspective of the health and social care sector and from a wider societal perspective. The forms will include the costs of health and social care (service provision and use of other health and social care services) and take account of productivity costs (time away from work) and out of pocket expenditures incurred by the patients (for example, travel expenses, over the counter medicines and supplements and additional costs/savings of any dietary changes).

Given the anticipated close involvement of supporters in the self-management process the burden to the supporter will also be taken account of. This will include productivity costs and out of pocket expenses incurred by the supporter. In respect of supporter costs it is anticipated that the questions relating to this will form part of the participant's questionnaire. There is precedence for this in previous studies in self-management (for example within the Client Service Receipt Inventory administered as part of an arthritis self-management intervention undertaken by Royal Free & University College Medical School (personal correspondence from Martin Knapp)). However, the work undertaken in Phase I will inform how this data is collected and we do not rule out asking the supporters themselves to complete a separate data collection form. All data collected during Phase I will be handled by LIHS, except for the medical records form which will be handled by the CTRU.

4.9 OUTCOMES

At the end of Phase I we will have:

- A robust estimate of the numbers of people who meet our criteria, and the numbers willing to consider change and to participate in further research.
- We will be able to characterize the population in terms of important characteristics such as diabetes control, living circumstances and presence and involvement of a supporter in diabetes management.
- We will have developed our self-management materials and adherence measure and field-tested them for acceptability in service users from our PPI collaborators.

4.10 STATISTICAL CONSIDERATIONS

4.10.1 SAMPLE SIZE

We initially aimed to interview 350 people meeting our eligibility criteria. This number would allow us to estimate the proportion eligible of the target population (i.e. conservatively 50%) for Phase II to at least within 5.2% with a 2-sided 95% confidence interval. If only 200 are achieved, the width of this confidence interval increases, and reduces precision to 6.9%.

4.10.2 GENERAL CONSIDERATIONS

Statistical analysis is the responsibility of the CTRU Statistician. The analysis plan outlined in this section will be reviewed and a final statistical analysis plan will be written before any analysis is undertaken. The analysis plan will be written in accordance with current CTRU standard operating procedures and will be finalised and agreed by the following people: the trial statistician and supervising statistician, the Chief Investigator, the CTRU Lead Methodologist and the Trial Co-ordinator. Any changes to the finalised analysis plan and reasons for change will be documented.

4.10.3 PRIMARY ANALYSES

Analysis will focus on descriptive statistics and confidence interval (CI) estimation rather than formal hypothesis testing.

To evaluate a simple case-finding method to identify participants, the pattern and prevalence of uncertainty during eligibility assessments, methods of identification of participants, contacts (including number, duration, and type), duplicate referrals, and clusters of referrals will be summarised overall and by role of referrer and region where appropriate.

To provide *a* robust estimate of eligibility, screening, referral, interview, eligibility, capacity, consent and registration rates will be reported. Consent will be sub-divided into those willing to consider change and those willing to participate in further research. The flow of participants and supports through the study will be depicted in a CONSORT diagram.

The eligible population will be characterised based upon the summary of diabetes control (i.e. HbA1c), demographics, living circumstances, and presence and involvement of a supporter in diabetes management, both overall and by whether the person wants help and by whether consent is given to be contacted in phase II.

Candidate outcome measures of diabetes control available in routine care will be summarised in terms of data quality, including HbA1c by weight, tablets and level of exercise.

Acceptability of the outcome measure will be assessed by the presence of missing items in the records of participants randomised to receive supported self-management

5 PHASE II – FEASIBILITY RCT

5.1 OBJECTIVES

To undertake a feasibility RCT

1. To estimate recruitment and retention rates for a definitive Phase III trial
2. To assess the feasibility of collecting a range of physiological, psychological, behavioural and cost-effectiveness outcome measures and maintaining the blind for subjective outcomes
3. To develop a checklist of potential negative outcomes and a related process for their collection, with a preliminary assessment of the acceptability of the intervention
4. To measure the variability in the main outcomes (especially HbA1c, BP, BMI, and EQ-5D
5. To test the performance of the data collection forms developed and the feasibility of collecting data from medical records.
6. To assess the feasibility of delivering/receiving the intervention (via adherence, drop-outs and negative outcomes such as distress and agitation).
7. To test the feasibility of using a standardised adherence measure to assess delivery and use of self-management techniques
8. To provide a detailed description of what treatment is delivered to each arm

9. If appropriate, to assess proof of concept (PoC) in relation to potential efficacy of the intervention
10. If appropriate, to develop the resources for an RCT aimed at evaluating the clinical and cost-effectiveness of the manualised intervention, including a trial protocol and information sheets.

5.2 DESIGN

An individually-randomised feasibility RCT of manualised supported self-management plus treatment as usual (MSSM+TAU) versus TAU (TAU), involving 150 participants (and, where possible, their supporters) recruited during phase I who consent to take part.

Eligible, consenting participants and their supporters (if available and willing) will be randomised on a 1:1 basis and followed up for a period of up to 12months. Participants, supporters, referrers and care providers cannot be blinded to treatment allocation, however, steps will be made to blind all aspects of outcome assessment carried out by Study Researchers. To avoid un-blinding the Study Researchers, the Research Nurse will pass data about the intervention (including adherence) directly to the CTRU. Data will be collected from medical notes, by the Research Nurse and/or by Study Researcher interview. Along with data on variability of outcomes and recruitment rates, these data and detail regarding appropriate data collection methods and therapeutic delivery will be used to inform the design of a definitive, multicentre RCT.

If any of the following criteria are met, we will not proceed to a main RCT application:

- Recruitment of 20 or fewer participants by end of the first 6 months of Phase II
- Active or passive withdrawal from Researcher follow-up of 40% of recruited participants
- No attendance by 50% or more participants in the manualised intervention

Otherwise we will use the data we collect to optimise the trial protocol going forward. For example, if more than 20% of QOF reviews are unable to be timed to take place within 1 month of the target follow-up visit we will consider not using HbA1c or BMI as the primary outcome. Ease of collection of candidate primary outcomes, their data quality and clinical importance will be used to choose a primary outcome for the main RCT.

5.3 PARTICIPANT ELIGIBILITY

5.3.1 INCLUSION CRITERIA

Participants found to be eligible in Phase I, meeting the following criteria, are eligible for entry, providing they do not meet any of the exclusion criteria:

- Providing written or verbal (where necessary) informed consent (assessment of mental capacity to consent will be repeated by the Study Researchers)
- Having up-to-date (ideally within 6 wks of randomisation) routine values of HbA1c and BMI or being willing to undergo a blood test and measurements to establish HbA1c and BMI.
- Having suboptimal diabetes control defined as HbA1c >6.5% (equivalent to 47.5 mmol/mol) OR BMI > 25 OR physical activity below national guidelines.

5.3.2 EXCLUSION CRITERIA

Participants meeting any of the following criteria will not be eligible for entry:

- Referred for insulin or put on insulin between identification and randomisation, or likely to require insulin in the next 6 months
- Not living in the community at randomisation
- Declining further assistance with diabetes self-management

5.4 SUPPORTER ELIGIBILITY

5.4.1 INCLUSION CRITERIA

- An operational definition of 'a key person in providing regular practical support in diabetes self-management, who is in contact with the person with diabetes at least weekly'
- Able to give informed consent

For the purposes of Phase II we will identify one main named supporter with whom to conduct the baseline assessment, although we recognize there may be several people involved with relevant aspects of a participant's life (diet, physical activity, clinic attendance and so on). Such people may be included *ad hoc* as *"other helpers"* in self-management plans if desired by the participant but will not be defined as a key supporter. If there is no other named supporter, this will be recorded in a CRF and incorporated into the analysis. .

5.5 RECRUITMENT

All eligible and consenting participants and their supporters (where applicable, supporters may differ from those in Phase I) from those identified in Phase I will be recruited into the feasibility RCT. Participating Trusts will be required to obtain local management approvals and will be provided with appropriate information to confirm their role and what information we might need from them by the Study Researchers.

1) To maximise recruitment of participants into the trial, two routes will be used for collecting up-to-date blood results: Where possible, participants will be recruited in accordance with the date of their next QOF assessment (approximated from the date of their QOF assessment from Phase I) to assist in the coordination of participants next QOF assessment within 6 weeks of participants 12 months follow up visit. Baseline, 6 and 12 month blood results are taken from medical notes, wherever possible, with the back-up of research blood tests.
2) Participants will be recruited following consent to a research nurse taking blood at baseline, 6 and 12 months. Here, participant results in medical records will be used as back-up where available.

5.5.1 RECRUITMENT PROCESS

For people identified in Phase I as willing to consider further participation in research, and identified as willing to consider help in looking after their diabetes, the Study Researcher will mail out Phase II information sheets with a covering letter, timed according to dates of recent blood tests (Route #1). Note that Phase I will continue during the recruitment period of Phase II, and mail will only be sent to participants who indicate that they would be happy to receive letters. Approximately a week later (for those sent letters) or as the first re-contact (for those not sent letters), a Study Researcher will approach those identified by phone and establish interest and eligibility. The study researcher may record first names of supporters if it is helpful to establish participant agreement. For example a support worker may state that it would be better to contact a participant's Key Worker who is currently not available. In this case the Key Worker's first name will be recorded so they can be asked for at a follow up call. No other identifying information will be recorded about that person until after their consent is taken. The Study Researcher will then meet the person to gain separate consent to participation in the feasibility RCT, to confirm eligibility, to collect baseline data and, for those in Route #2, consent for a nurse to visit and take bloods and other physical measures (BP, height, weight, waist to hip ratio) prior to randomisation. If they have an identified supporter we will recruit both the person with diabetes and their supporter, if both consent. If they do not have an identified supporter or an identified supporter declines participation we will recruit just the person

with diabetes. It is anticipated that there may be a change in supporter from baseline to follow-up, therefore the same recruitment and consenting process will be undertaken for any new supporters at follow-up.

The Research Nurse will visit the participant after they have given consent to the Study Researcher. S/he will explain the process of taking the physical measurements and reconfirm consent. They will have been trained by service users groups to explain the tests in a way that is acceptable to this patient group. S/he will then take bloods and other physical measures if consent has been given. The participant has the right to refuse these measures being taken at any time. If the participant refuses to have the measures taken the Research Nurse will offer the following options: agree to all other measures except blood; agree to have bloods/measures taken at their GP practice; agree to have bloods/measures taken at the Research Nurse base in Leeds University, decline all measures and do not take part in the study. Note that participants cannot enter the trial without an up-to-date blood result for HbA1c.

5.5.2 INFORMED CONSENT

The Study Researchers and Research Nurses will be appropriately trained to assess mental capacity. We will include in Phase II only those with the capacity to consent to the research and to undertake an element of self-management. Capacity required for Phase II will be higher than that for Phase I, since participation in Phase II will involve a greater cognitive ability. This judgement will be made by the Study Researcher, who is familiar with the MSSM intervention and will know what level of capacity is needed for meaningful participation. We will also attempt to obtain consent from a supporter when that person supports diabetes self-management and is willing to be involved in the study. They will consent to assist the person with diabetes in any changes agreed during MSSM, and to participate as agreed in the project by (for example) assisting in collection of materials such as completed planning charts. The Participant Information Booklet will be discussed with both person with diabetes and their supporter (if present) and they will be offered several opportunities to ask questions throughout the discussion of the booklet. Informed consent will be taken prior to any baseline data being collected for Phase II. Consent will be reassessed by the Study Researcher and Research Nurse at each follow-up.

We will meet expenses of participants, ensuring that we handle cash transfers suitably, reimbursing reasonable travel costs and not incentivising participation through payment.

For each consenting participant we will offer contact with a research advocate who is independent of the research team and whom we will ask to ensure that the person remains happy to participate throughout the conduct of the trial and follow-up. This advocate will be a member of the 3rd sector organisation People in Action (PiA). The participant will be given a contact telephone number for PiA and asked if they would like an initial contact.

The participant will be assured that they will continue to receive the same quality of care regardless of whether or not they are eligible for the study. The right of the participant to refuse consent without giving reasons will be respected. The participant will also remain free to withdraw from the study at any time without giving reasons and without prejudicing any further treatment. The responsibility for the overall care of the participant remains with the attending clinical team. If the participant agrees to participate then written informed consent will be obtained. Verbal consent will be obtained (where necessary) only when consent is clearly given but the participant cannot provide a signature or initials. This has proven a necessary approach in Phase 1 as some participants cannot grip a pen or write their names. In these circumstances, when it is established they cannot give written consent, verbal consent will be accepted.

The original consent forms will be held centrally at the CTRU. The Study Researcher will make copies of the original consent form for themselves. The Study Researcher will send the participant a certificate of participation and their GP a letter confirming consent. A copy of the consent form will

be available to the participant and their GP on request.

5.6 RANDOMISATION

Eligible participants will be randomised following informed consent and baseline assessment on a 1:1 basis to receive manualised supported self-management plus treatment as usual (MSSM+TAU) or treatment as usual (TAU) by the Study Researchers using a secure, automated 24-hour telephone randomisation service based at the CTRU, University of Leeds. This will ensure allocation concealment. Authorisation and PIN codes will be required to access the randomisation system and will be provided by the CTRU when all relevant study approvals are in place. . A computer-generated adaptive minimisation algorithm incorporating a random element will be used, accounting for the following factors

- Site (Leeds, Bradford, Wakefield)
- Supporter (None, not living with supporter, living with supporter).
- HbA1c (<6.5, 6.5 to 8.5, >8.5)
- BMI (<=25, >25)
- Physical activity (below, above national guidelines)

The following details will be required at randomisation:

- Name of Researcher (who obtained informed consent and conducted baseline assessment and undertaking randomisation)
- GP/NIHR site code
- Phase I ID
- Patient details: Initials and date of birth
- Supporter (None, not living with supporter, living with supporter)
- Recent HbA1c
- Recent BMI
- Recent Physical activity (below, above national guidelines)
- Confirmation of eligibility for Phase II (patient and supporter as applicable)
- Confirmation of informed consent for Phase II (patient and supporter as applicable)

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Baseline data will be collected via a face-to-face interview with a Study Researcher and (where applicable) the Research Nurse. The Study Researcher or Research Nurse will phone the 24-hour telephone service after the final visit. The CTRU will inform the Research Nurse, but not the Study Researcher, of the outcome of randomisation. The Research Nurse will contact the participants (supporters and advocates, as appropriate) in the intervention and control arms to explain this outcome and to make an appointment with those in the intervention arm. Randomised participants will receive treatment as specified in section 5.7. We will inform GPs of participant participation by letter at the time of randomisation.

5.7 TREATMENT DETAILS

5.7.1 MANUALISED SUPPORTED SELF-MANAGEMENT (MSSM)

For those randomised to intervention we will arrange the professional support element via a Research Nurse. One or two dedicated Research Nurses will provide support to participants across sites. They will be linked to the participant for the purposes of the analysis. Supervision and training will be given by the Chief Investigator and co-investigators (details can be found the Intervention Manual).

The intervention has four standardised components with associated materials (details can be found in the Intervention Manual); how they are delivered will depend upon participant and supporter characteristics and preferences (details of the tailoring algorithm are given in the Intervention Manual). The Research Nurse will work through the elements of supported self-management with the participant, explaining how to use the materials and suggesting some initial actions and activities. Further contact will be negotiated but we anticipate a total of 3-4 meetings of 30-60 minutes over 6-8 weeks, followed by telephone support and advice – the balance offered to the person with diabetes to be decided by negotiation.

MSSM aims to work with a supporter, identified at baseline. This supporter's involvement with the participant and suitability to be the named supporter in the intervention will be assessed and agreed with the participant during the first intervention session. The supporter may be a family member or a member of staff employed by a care provider, perhaps both, but (for the purposes of the RCT) no more than two people will be named. One component of the intervention involves a session with named supporters, explaining the participant's plans and sharing with them the relevant materials – so that they can support the participant in their plans.

Additionally other people may also be involved on a more intermittent or informal basis and need not be somebody who has consented to participate in the trial formally. For example somebody may be invited to assist the participant's plans to implement the intervention with the participant's approval, such as going for a weekly walk with them or accompanying them to a swimming class.

5.7.2 STANDARD LEAFLET (SL)

We will ensure that a standard information leaflet about type 2 diabetes aimed at people with LD is provided to those all participants . This leaflet will be one selected from those produced by the NHS, by Diabetes UK or a LD charity and will cover the key areas already identified as essential in diabetes self-management. That is, diet, exercise, medication use, and feet and eye care. The leaflet will be selected by our PPI collaborators from the range we have identified as part of the review of materials in Phase I. We will not otherwise attempt to influence the content of treatment as usual.

5.7.3 TREATMENT AS USUAL (TAU)

All participants randomised into the RCT will receive treatment as usual. Different staff will be involved in providing treatment as usual because uncomplicated type 2 diabetes in the community is managed through primary care. Little is currently known about the general level of care delivered at a local level. One of the objectives of Phase II will be to provide a detailed description of what is delivered to each arm, including a checklist of health care professionals involved, by centre and level (primary, secondary and third sector organisation), and a list of their associated tasks.

5.8 MONITORING ADHERENCE TO TREATMENT DELIVERY

We will record steps taken to ensure consistency in use of the MSSM – training and supervision sessions with research nurses; annotation of the manual by research nurses; other experience and training in diabetes or LD care prior to Phase 2.

Adherence to the supported self-management programme involves participant, supporters and Research Nurse

Provider adherence will be recorded in CRFs completed by the Research Nurse and signed off by a supervisor of the Research Nurse (e.g. the Chief Investigator) recording

- the dates of treatment meetings,
- all telephone contacts,

- materials provided in particular: goal-setting sheets; weekly planning charts and self-monitoring charts.
- Written confirmation any named supporter has received an information pack

Participant/Supporter adherence will be collected by the Research Nurse or a supporter. Evidence of use of the techniques of self-management will be identified by copying and/or collecting: individual goal-setting chart; weekly planning chart; self-monitoring chart.

Data will be entered onto a proforma derived from the *OK-diabetes adherence record*. We will develop a coding and scoring system, aiming for a global rating of overall adherence on a short ordinal scale.

We will supplement the quantitative data with questions in a section of the topic guide for the qualitative interviews with all trial participants.

5.9 WITHDRAWAL

There are not a fixed number of meetings for the manualised supported self-management (MSSM) intervention as this will be negotiated between the participant, their supporters (where appropriate) and the Research Nurse. Participants and supporters may choose not to see the Research Nurse or continue with the self-management intervention but this does not constitute treatment withdrawal as such. Therefore we will simply record the intervention received. Similarly, there is no opportunity for participants to withdraw from the standard leaflet (SL) or from treatment as usual (TAU). So we will just monitor intervention received here as well as part of the data collection process. Where participants wish to withdraw from study follow-up, the type of withdrawal will be clarified (one or more of withdrawal from: clinical records follow-up, researcher interview, Research Nurse tests and measures) and subsequent data collected accordingly. If a supporter wishes to withdraw consent to participation in the feasibility RCT, participants will be asked by the Study Researcher whether they would like to discuss their options with a research advocate. A wider discussion will then take place including the Study Researcher and the participant will be re-consented.

The Study Researchers will make every effort to ensure that the specific wishes of any participant or supporter who wishes to withdraw consent for further involvement in the trial are defined and documented using the Withdrawal CRF in order that the correct processes are followed by the Study Researchers and CTRU following the withdrawal of consent.

Where capacity to participate is lost during the feasibility RCT, the participant will be withdrawn from the study, and no further data collected. Repeated formal assessment of capacity will not be undertaken routinely – but a new capacity assessment will be undertaken if there are expressions of concern from any relevant 3rd party or if a new event raises the possibility of loss of capacity. Data collected up to the point of loss of capacity will be included as per the participant's original wishes.

5.10 DATA COLLECTION / ASSESSMENTS

Participating sites will be provided with the required documentation by the Study Researcher or CTRU. They will keep copies of all Case Report Forms (CRFs) for the study which have been completed by the Research Nurse. The Study Researcher will keep copies of all CRFs completed by the Study Researcher.

The file of essential study documentation (Trial Master File), the original consent forms and originals of Case Report Forms (CRFs) will be stored centrally at the CTRU. Assessments will be undertaken at the following time points:

- Medical notes review/check (prior to randomisation)
- Pre-baseline phone call (prior to randomisation)

- Baseline interview (prior to randomisation)
- Research Nurse visit to take physical measures (where necessary, prior to randomisation)
- 6 Month Follow-up interview & Qualitative interview
- 6 Month research nurse/medical follow-up
- 12 Month Follow-up interview & Qualitative interview
-
- 12 Month research nurse/medical follow-up

with a guidance window of plus or minus two weeks at follow-up (baseline interviews should take place no more than six weeks prior to randomisation). If up-to-date Phase I medical records (specifically HbA1c and BMI) are available, they may be carried forward to the Phase II baseline. If not, participants will be asked to undergo a blood test with the Research Nurse to establish baseline physical measures. All participants will be offered anaesthetic cream for the blood test. If the participant declines the physical measures, the Research nurse will establish if recent HbA1c and BMI (and other secondary physical measures outlined in the table below) are available from their GP (ideally less than 6 weeks old at the point of randomisation). If they are, they may be carried forward to the Phase II baseline. Wherever possible, baseline data will be synchronised with the annual GP QOF review to take place within 1 month of the target 12 month follow-up visit.

Table 2: Phase II Baseline and Follow-Up Assessments

	Med notes review /check	**Pre-baseline phonecall**	**Baseline interview**	**Nurse baseline**	**6 & 12month Medical/ Nurse Follow Up**	**6 & 12 month Follow up Interview**	**Med notes follow up**
Eligibility and consent							
Presence and role of a supporter and/or research advocate			X			X	
Mental capacity to consent to Phase II (P, R)			X				
Eligibility for Phase II (assessed by Study Researcher)	X	X	X				
Consent for Phase II (P, S, R*)			X				
Follow-up data (P, S, R, N)							
Negative outcomes[$]						X	
Related and Unexpected Serious Adverse Events						X	
Hospital attendances						X	
Current physical health state (e.g. HbA1c, BP, BMI, , , , , , weight, BP, HbA1C, cholesterol, HDL/ LDL triglycerides, Urea and Electrolytes, waist to hip ratio (N)	X			X	X		
Thyroid function, height (N)				X			
Q Risk, Retinal screening, Medication, Serum creatinine, micro-albuminuria							X
Details of Treatment Received						X	
Adherence to the intervention (N)						X	
Prescribed diabetes regime (diet, exercise)						X	
Questionnaires (completed at Researcher visit)							
Health Economics questionnaire (P&S interviewer administered) to cover health and social care costs, participant and supporter expenses and productivity costs			X			X	
Participant (P) mood (questions			X			X	

taken from Phase I)							
Health-related quality of life (EQ5D) (P)			X			X	

* P = Participant, S = Supporter, R = Researcher, N=Research Nurse

Qualitative interview
We will interview all participants in the self-management arm using a relatively simple topic guide and framework analysis to identify themes related to both positive and negative experiences of implementing self-management. The purpose of the interview is to identify elements of the intervention that were popular and easy to adhere to and those that were difficult or unpopular or insufficiently supported. All participants will be interviewed to characterise treatment as usual.

5.11 PARTICIPANT QUESTIONNAIRES

The following standard assessment instruments will be incorporated into assessment packs.

EuroQol-5D (EQ-5D™) [18]

The EQ-5D™ from the EuroQol Group is a standardised, non-disease-specific self-report questionnaire for describing and valuing health. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile consisting of 5 dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each having three levels.

5.12 FOLLOW-UP PROCESSES

Participants, and their supporters, will be followed up directly by the Study Researchers and at separate visits by the blinded Research Nurse to collect bloods, where appropriate, once at 6-months post-randomisation and once at 12-months post-randomisation. Data will be collected by interview in clinic or at the participant's home or at a place of their choosing. Hip and waist measurements will be taken by the Study Researchers (blinded) using a standard protocol. All participants who enter the study will be considered part of the intention to treat population and efforts will be made to follow them up wherever appropriate.

If there are no up-to-date medical records, then the blinded Research Nurse will visit to collect weight, BP, HbA1C, cholesterol, HDL/LDL triglycerides, Urea and Electrolytes. All bloods will be collected in one venepuncture. If the participant refuses to undergo these measures with the Research Nurse, we will request this data from their GP (ideally it will be within 6 weeks of the visit date).

5.13 HEALTH ECONOMICS

The feasibility RCT will be used to test the performance of the data collection forms developed. Performance will be defined in Phase I and it is anticipated that it will include assessment of clarity of concept (as evidenced by number of missing data (> 75% completed)). Integral to this part of the study is the acceptability of the data collection forms to participants and their supporters/informal carers - whether they contain relevant information (evidenced by completion).

Whilst the primary aim of Phase II is to test the feasibility of data collection for any subsequent RCT, analysis of the data collected will include descriptive statistics of the resources used. In addition to the participant/supporter completed data, the resources associated with development and delivery of the intervention will be recorded. These will be based on routine data such as administrative records and participant records, as well as a detailed description of the development process. For both sets of data unit costs for health service resources will be obtained from national sources such as the PSSRU, the BNF and NHS Reference cost database. Where national unit costs are not available the finance departments of trusts participating in the study will be asked to provide local cost data. The mean of these costs will be used as the unit cost estimate in the analysis. Within this

Phase II analysis we will follow the NICE methods guidance [21] in as much as the perspective of the NHS and personal social services would be taken but additional analysis would adopt a societal perspective.

In line with NICE current recommended practice any subsequent cost effectiveness analysis in a definitive RCT will require production of quality adjusted life years (QALYs). The estimation of QALYs requires utility weights for each health state observed in a trial population. A 2001 Health Technology Assessment report that considered general health status measures for cognitively impaired populations found the EQ-5D to be superior compared with other preference-based measures of health [22]. We will explore use of the EQ-5D. Additionally, again given their anticipated close involvement in the self-management process and potential impact on their health related quality of life, we will also explore the feasibility of use of the EQ-5D for supporters/informal carers. This will not include 'paid' carers/ supporters.

The resource use questionnaire will be interview administered at baseline and the 6 and 12 months follow up together with the EQ-5D.

5.14 OUTCOMES

This feasibility RCT will inform the choice of primary outcome for the definitive RCT. The outcomes here relate to feasibility of recruitment, retention, intervention delivery and outcome data collection:

Recruitment and retention

- Number of Phase I participants screened for eligibility for Phase II
- Proportion of Phase I participants screened found to be eligible for Phase II
- Proportion of Phase I participants that consent to Phase II out of those found eligible
- Proportion of Phase I participants randomised out of those that consent
- Proportion of randomised participants that have a supporter
- Reasons for non-participation (participant and supporter)
- Method of identification for randomised participants and supporters
- Proportion of randomised Phase II participants with all the required baseline and follow-up assessments completed, number of physical measures refused, number of withdrawals from follow-up data collection, reasons for withdrawal, number of losses to follow-up

Intervention delivery

- Proportion of participants randomised to the MSSM+TAU arm attending at least one session of MSSM with the Research Nurse, number of drop-outs from MSSM, reasons for drop outs
- Agreed method of measuring participant, supporter and research nurse adherence to MSSM including uptake/adherence rates and assessment of the feasibility of using a standardised measure
- Detailed description of what treatment was delivered to and received by each arm, including a comparison of TAU across arms and an assessment of the feasibility of collecting data on TAU pathways
- Preliminary assessment of the acceptability of the intervention, including negative outcomes, hospital attendances and RUSAEs.

Outcome data collection

- Assessment of the feasibility of blinding Study Researchers to treatment allocation
- Proportion of participants who refuse physical measures with available and timely QOF data at baseline and (if necessary) at their follow-up assessments

- Assessment of the feasibility of collecting data on adherence to MSSM and SL.
- Completion rates for other data collected, including assessment of the feasibility of collecting health economics data (e.g. participant EQ-5D, NHS and supporter costs, medication use)
- Missing item level data on self-reported questionnaires

Statistical outcomes

- Variability of candidate primary and secondary outcomes at 6 and 12 months post-randomisation (e.g. HbA1c, BP, BMI, waist to hip ratio, EQ-5D, vascular/microvascular risk markers, marker of microvascular disease, participant mood)
- Proportion of participants classed as abnormal on standard criteria for medical markers
- Assessment of the potential for contamination within households

Proof of concept outcomes

- Change in HbA1c at 6 months post-randomisation (primary)
- Change in BP, BMI or Total Cholesterol at 6 months post-randomisation (secondary)

Qualitative outcomes

- Positive and negative experiences of implementing self-management
- Perceptions of Standard Leaflet and experience of being TAU arm
- Further detail regarding TAU in all participants
- Modified implementation plan for the definitive trial.

5.15 STATISTICAL CONSIDERATIONS

5.15.1 SAMPLE SIZE

To address the feasibility objectives, we planned to recruit 80 participants in total, randomised equally between intervention and control groups, in order to obtain follow-up data on at least 30 participants per group as recommended by Lancaster et al [24]. This assumes loss to follow-up will be no greater than 25% at 6 months. We now plan to recruit 150 participants in total, randomised equally between intervention and control groups. Part of the rationale for the feasibility RCT was to inform the design of a definitive RCT. That is, robust estimates for non-compliance and loss to follow-up rates in this patient group will feed into power calculations. This will still be the case, but the intention now is that the feasibility RCT will also address proof of concept.

To address the proof of concept objective, we will use methods developed for phase II screening trials in oncology [Rubinstein 2005] in which preliminary and non-definitive randomised treatment comparisons are made, carefully adjusting the false-positive (α) and false-negative (β) error rates so the target treatment effect is appropriate whilst the sample size remains restricted. We assume a reduction of HbA1c by 0.5% or more at 6 months would be clinically important. This change from our initial application, when we quoted 1% as a desirable change, is based upon clinical advice from our co-I Ramzi Ajjan and is equivalent to an effect size of 0.33 based upon data from the ADVANCE trial and preliminary data from Phase I. Allowing for 25% loss to follow-up (refusal of blood tests or researcher visit), 150 patients would adequately power (82%) us to detect a reduction in the primary outcome of HbA1c of 0.5% for the intervention compared to control, assuming a common standard deviation of 1.5% (as per ACCORD [Gerstein 2008]), using a 1-sided t-test with a significance level of 20% to test for this degree of superiority. If the decision is made to continue to a full trial, this cohort would form an internal pilot for the main RCT. The sample size for the main trial will be revisited at a later date.

5.15.2 ANALYSIS POPULATIONS

The Intention to Treat (ITT) population is defined as all patients randomised to treatment regardless of uptake of the intervention, non-compliance or loss due to withdrawal. All participants will be analysed according to the treatment they were randomised to. All analyses and data summaries will be carried out using the ITT population.

5.15.3 SUB-GROUP ANALYSES

There are no planned sub-group analyses.

5.15.4 INTERIM ANALYSES

No interim analyses were planned. Following the request from the funders to consider extending the feasibility RCT to assess proof of concept, the following interim analyses are planned:

1) **Decision point 1** (1st March 2015): We will decide whether to proceed beyond our original feasibility target to recruit N=150 participants. We will proceed if
    a. We have recruited as expected N>=70, with acceptance rate indicating we can recruit to target from the remaining Phase I participants
    b. Willingness to take up the intervention makes it plausible that there could be an effect, that is >75% adherence to therapy appointments

    If we proceed to recruit N=150 then we also need to plan to follow-up the whole sample for 12 months instead of the originally planned 6 month follow-up.

2) **Decision point 2** (1st December 2015): We will decide whether to start set-up for the main trial, based on interim analyses of the 6 month outcome data for the first 75-80 participants reviewed by the DMEC.

3) **Decision point 3** (1st June 2016): We will decide whether to proceed to the main trial based on interim analyses of the 6 month outcome data for the full 150 participants reviewed by the DMEC.

An analysis plan will be drafted following the first decision point of all analyses to be reviewed by the DMEC. This will be agreed by the DMEC prior to their first meeting.

5.15.5 STATISTICAL ANALYSES

Final analysis will be conducted when all the available data has been received and cleaned on the intention-to-treat sample, including all randomised participants in the groups to which they were randomised.

Primary analysis

Recruitment, uptake and adherence rates will be reported overall and by arm and by recruiting site. Six and twelve-month follow-up rates will be reported for each outcome (for both participant and supporter, self-reported measures and those collected from routine GP data sources), also overall and by arm and site. The candidate primary outcomes for a definitive RCT of HbA1c, blood pressure (BP) and body mass index (BMI) will be summarised overall and by arm at baseline and 6 and 12 months and for the intervention arm by adherence to the manual at 6 months. Means and SDs, or medians and interquartile ranges, depending on the distribution, together with 95% CIs will be presented. This will provide more accurate estimates of variability, recruitment, follow-up and adherence rates needed to assess the feasibility of recruiting into, and inform the sample size estimation of, a definitive trial. To assess proof of concept, 80% one-sided confidence intervals will be presented for the change in HbA1C, BP, BMI and total cholesterol from baseline to 6 months follow up.

Feasibility and data quality outcomes

The feasibility and quality of collecting blood tests and vascular risk markers and markers of microvascular disease by the Research Nurse will be assessed and the proportion and nature of any missing data on these outcomes. The presence and quality of data collected on other outcomes will also be summarised, including adherence to the intervention at 6 and 12-months. This will help to inform the modes of data collection and the instruments used in the definitive trial.

Other outcomes

The outcomes of participant mood, negative outcomes and health-related quality of life, changes in treatment and patient and supporter/informal care costs will be reported using means and SDs, medians and interquartile ranges or frequencies and proportions, depending on their distributions, together with 95% CIs at baseline, 6 and 12 months both overall and by arm. This will characterise the randomised population at baseline and follow-up.

5.16 PARTICIPANT SAFETY

5.16.1 GENERAL DEFINITIONS

An adverse event (AE) is:

- any unintentional, unfavourable clinical sign or symptom
- any new illness or disease or the deterioration of existing disease or illness

A serious adverse event (SAE) is defined in general as an untoward event which:

- results in death
- is life threatening
- requires or prolongs existing hospitalisation
- is significantly or permanently disabling or incapacitating
- constitutes a congenital anomaly or a birth defect or
- is otherwise considered medically significant by the clinician.

A SAE occurring to a participant which, in the opinion of the Chief Investigator, is related and unexpected will be reported to the main Research Ethics Committee (main REC).

The National Research Ethics Service (NRES) defines related and unexpected SAEs (RUSAEs) as follows:

- 'Related' – that is, it resulted from administration of any research procedures; and
- 'Unexpected' – that is, the type of event is not listed in the protocol as an expected occurrence.

5.16.2 EXPECTED ADVERSE EVENTS AND REPORTING REQUIREMENTS

We anticipate very few risks to participants in both Phase I and II. In Phase I we do not intend to monitor safety as this does not involve any active intervention or researcher follow-up.

Expected non-serious adverse events occurring in phase II will be reported via study CRFs, and will be reported at the end of the trial. Expected non-serious AEs include:

- Significant increase in distress defined as a move to moderate/severe symptom levels or marked behaviour change
- Deterioration in diabetes care (i.e. increase in HbA1c, stopping taking tablets, deliberately missing meals, drinking too much, marked weight gain)

- Other deterioration in behaviour (such as agitation, aggression, shouting, substantial sleep disturbance, social withdrawal, self-harm) reported by participant or supporter to Study Researcher at follow up
- Falls occurring during new and unfamiliar increases in activity, usually with no or only minor injury e.g. grazes

In phase II people with diabetes where insulin is being considered are excluded, so that even if there is deterioration in diabetic control it should not lead to a medical emergency.

It is possible that the following potentially serious adverse events may occur during participation in phase II

	Expected event	**Reporting requirements**
1	A few people with rigid routines may be very upset by attempts to change these.	Levels of distress relating to the intervention & meeting SAE criteria will be reported by the Research nurse or other appropriate members of the clinical or research team on the appropriate CRF
2	It is possible that participants may occasionally attend A&E or be admitted to hospital; however this is unlikely to be a specific result of the intervention delivered in this study.	We will monitor hospital attendances, where these are related to a participant's diabetes, via completion of a Hospital Attendance form (GP or participant/supporter completed). (Where hospital attendance is deemed related to the intervention, we would expect an RUSAE form to be completed - see section 5.16.3.)
3	Death (as per normal population rates)	All deaths should be reported by the Study Researcher or relevant clinician (via fax*) to CTRU on a Death Form within 24 hours of research / clinical staff becoming aware of the event. The original form should also be posted to the CTRU in real time and a copy retained at site.
4	Self-harm	Instances of self-harm meeting SAE criteria will be reported by the Research nurse or other appropriate members of the clinical or research team on the appropriate CRF.
5	Hypoglycaemia	Those participants on sulphonylurea diabetes medication are at higher risk of hypoglycaemia than other type 2 diabetics especially if they skip meals or increase their exercise significantly. Participants will be asked about hypos by the researcher at follow up. Hypos relating to the intervention & meeting SAE criteria will be reported by the Research nurse or other appropriate members of the clinical or research team on the appropriate CRF

CTRU FAX NUMBER FOR REPORTING DEATHS: 0113 343 1737

Events detailed above should be reported from the date of consent to phase II participation, up to 12 months post-randomisation on the appropriate CRF (i.e. non-serious AE, distress, hospital attendance, death or RUSAE forms).

Death reports will be reviewed by the Chief Investigator (or appropriate clinical member of the PMG) within one working day of receipt by CTRU.

Deaths which, in the opinion of relevant members of the clinical team and / or the Chief Investigator, are related to the intervention will be subject to expedited reporting to the main REC and Sponsor within 15 days, as per the process for RUSAEs (detailed in section 5.16.3 below).

5.16.3 RELATED AND UNEXPECTED ADVERSE EVENTS

All related and unexpected SAEs (including deaths meeting RUSAE criteria) occurring from the date of consent up to 12 months post-randomisation must be recorded on the Related Unexpected Serious Adverse Event Form and faxed to the CTRU **within 24 hours** of the Research Nurse or research staff becoming aware of the event. The original form should also be posted to the CTRU in real time and a copy retained at site.

For each Related Unexpected SAE the following information will be collected:

- trial number
- full details in medical terms with a diagnosis, if possible
- its duration (start and end dates)
- action taken
- outcome

Any follow-up information should be faxed to CTRU as soon as it is available. Events will be followed up until the event has resolved or a final outcome has been reached. The original form will be filed centrally at the CTRU once the event is resolved.

CTRU FAX NUMBER FOR REPORTING RELATED/UNEXPECTED SERIOUS ADVERSE EVENTS: 0113 343 7985

All Related / Unexpected SAEs will be reviewed by the Chief Investigator (or other delegated clinical members of the PMG) and subject to expedited reporting to the main REC and Sponsor as per current NRES guidance, CTRU SOPS and Sponsor requirements. Process co-ordination and expedited reporting will be undertaken by the CTRU on behalf of the Chief Investigator within 15 days.

Responsibilities of the Chief Investigator, CTRU, TSC and Sponsor will be detailed in a study specific Work Instruction.

5.16.4 MONITORING AND REPORTING

In accordance with the TSC Terms of Reference, an appropriate sub-committee of the external members of the TSC will review safety data and serious breaches of GCP (as these arise) prior to their meetings. Should a DMEC be convened, then PoC review will become DMEC responsibility and a summary of all adverse events will be reported to the DMEC at the times of interim analyses review.

An annual summary of all events will also be reported to the TSC and Sponsor.

Safety issues will be reported to the Main REC in the annual progress report.

6 DEFINITION OF END OF STUDY

The end of the study is defined as the date of receipt of the last set of participant follow-up questionnaires or the date of last attempt to contact participants by the researcher (this will be a maximum of one month after the target date of the last participants 12 month follow-up).

7 DATA MONITORING

7.1 DATA MONITORING

Data will be monitored for quality and completeness by the CTRU, using established verification, validation and checking processes. Missing data will be chased until it is received, confirmed as not available, or the study is at analysis.

The CTRU reserve the right to intermittently conduct source data verification on a sample of participants. Source data verification will involve direct access to patient notes at the participating centres, and other relevant investigation reports.

A central monitoring schedule will be defined and agreed by Trial Steering Committee (TSC) and Project Management Group (PMG). This will detail the timing and content of reports to these committees and is likely to include recruitment, data compliance and safety reporting.

For a feasibility study, a separate Data Monitoring and Ethics Committee is not usually required. Rather, the TSC will take on a safety monitoring role, with the constitution of a sub-committee to review safety issues where this becomes necessary. This will be the case for phase II until the first decision point in March 2015. Should the trial proceed thereafter to the larger PoC stage, it would be important to have additional DMEC review of safety issues. This would take place at the times of interim analysis review.

Any safety concerns identified by the TSC must be reported to the REC and the Sponsor by CTRU within 15 days of identification, and appropriate action taken.

7.2 TRIAL STEERING COMMITTEE (TSC)

A TSC will be established to provide overall supervision of the study, in particular, study progress, adherence to protocol, patient safety, and consideration of new information. The committee plan to meet once during the set-up period, once during Phase I, once at the end of Phase I and twice during Phase II (4 times in total). A subcommittee of the TSC will be convened where necessary to monitor safety data. A Trial Monitoring Plan will be developed and agreed by the Project Management Group and TSC based on the trial risk assessment; this may include on-site monitoring.

7.3 DATA MONITORING COMMITTEE (DMEC)

Following the first decision point (i.e. 1st Match 2015), the TSC will establish an independent DMEC to consider unblinded outcome data at the second two decision points (i.e. 1st December 2015 and 1st June 2017).

7.4 CLINICAL GOVERNANCE ISSUES

To ensure responsibility and accountability for the overall quality of care received by participants during the study period, clinical governance issues pertaining to all aspect of routine management will be brought to the attention of the TSC, and where applicable to individual NHS Trusts and sponsor.

8 QUALITY ASSURANCE AND ETHICAL CONSIDERATIONS

8.1 QUALITY ASSURANCE

The study will be conducted in accordance with the principles of Good Clinical Practice (GCP) in clinical trials, NHS Research Governance Framework, and through adherence to CTRU standard operating procedures (SOPs) and study-specific work instructions.

8.2 SERIOUS BREACHES

Investigators are required to promptly notify the CTRU of a serious breach (as defined in the latest version of the National Research Ethics Service (NRES) SOP). A 'serious breach' is defined as a breach of the protocol or of the conditions or principles of GCP (or equivalent standards for conduct of non-CTIMPs) which is likely to affect to a significant degree the safety or physical or mental integrity of the study participants, or the scientific value of the research. In the event of doubt or for further information, the Investigator or Study Researcher should contact the Senior Trial Manager at the CTRU.

8.3 ETHICAL CONSIDERATIONS

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, and October 2000. Informed written consent will be obtained from participants prior to registration into Phase I and randomisation into Phase II. The right of the patient to refuse participation without giving reasons must be respected. The patient must remain free to withdraw from the study at any time without giving reasons and without prejudicing their care or treatment. The study will be submitted to and approved by a main Research Ethics Committee (MREC) and the appropriate Site Specific Assessor for each participating site prior to entering participants into the study. LIHS will provide the MREC with a copy of the final protocol, participant information sheets, consent forms and all other relevant study documentation.

9 CONFIDENTIALITY

All information collected during the course of the study will be kept strictly confidential. Originals of information will be held securely on paper and electronically at the Clinical Trials Research Unit (CTRU). The CTRU will comply with all aspects of the 1998 Data Protection Act and operationally this will include:

- Consent from participants and supporters to record personal details including name, date of birth, address and telephone numbers, NHS number, hospital number(s), GP name, address and telephone number
- Appropriate storage, restricted access and disposal arrangements for participants' personal and clinical details
- Consent from participants for access to their medical records by responsible individuals from the research staff or from regulatory authorities, where it is relevant to study participation
- Consent from participants and supporters for the data collected for the study to be used to

evaluate safety and develop new research.

- Participants' and supporter's names, address and telephone numbers will be collected when a participant is referred to the study but all other data collection forms that are transferred to or from the CTRU will be coded with a study number and will include two identifiers, usually the participant's initials and date of birth.
- Where anonymisation of documentation is required, sites are responsible for ensuring only the instructed identifiers are present before sending to CTRU.

If a participant or supporter withdraws consent for further collection of data, their data will remain on file and will be included in the final study analysis.

9.1 ARCHIVING

At the end of the study, data will be securely archived at the CTRU, LIHS and participating centres for a minimum of 6 years.

10 STATEMENT OF INDEMNITY

This study is sponsored by the University of Leeds who will be liable for negligent harm caused by the design of the study. The NHS has a duty of care to patients treated, whether or not the patient is taking part in a clinical study, and the NHS remains liable for clinical negligence and other negligent harm to patients under this duty of care.

11 PATIENT AND PUBLIC INVOLVEMENT

The involvement of third sector organisations (and the people with Learning Disability that they support) will be essential to the success of this project. They will be involved in case finding activities, in the design and development of the manualised intervention, support recruitment to the feasibility trial and help develop trial information and consent materials/procedures. We are working with two partners from key local third sector organisations. Both partners were actively involved in the development of this proposal, supported by an NIHR Research Design Service Yorkshire and Humber Public Involvement in Grant Applications Funding Award.

The first is the chief executive of People in Action, a local organisation that provides services to young people and participants with Learning Disability and their families in education and learning, health and social well-being and independent living. They are also a leading organisation in the development of services for people with Learning Disability from black and minority ethnic communities in the area. The second is the Manager of the local umbrella organisation Tenfold through which the team will have access to around 90 local voluntary sector groups, each supporting people with Learning Disability, and their families. This will facilitate the case finding activities in Phase 1. Both third sector partners are represented on the Healthy Leeds Partnership Board, a strategic partnership for health improvement and the reduction of health inequalities. Board members include statutory partners, service user and carer representatives, the voluntary and community sector and other key health agencies. These links will be important in terms of facilitating the case finding phase and in raising awareness of the project more widely. In addition, People in Action are providing a research advocacy service for Phase II. The research advocate is an independent person who can help the person with LD consider their initial participation in the study (or not), and/or withdrawal if they no longer want to be involved. This is considered good practice in research where participants may find it particularly difficult to 'say no' to health professionals/ researchers. Each participant will be given the contact details of the advocacy service and an

explanation of what they do.

We also have the support of the Commissioning Manager Learning Disabilities & Autism, Leeds Clinical Commissioning Groups Network. Commissioning Managers are charged with the development of fair and accessible health services, including the provision of advice, information and signposting. Developing an effective supported self-management intervention for people with type 2 diabetes and Learning Disability would make an important contribution in this area. He has agreed to actively support the project, for example facilitating access to service user and carer groups already set up to support the Leeds Learning Disability Strategy. He also sits on the Healthy Leeds Partnership Board with our third sector partners.

Third sector organisations and people with Learning Disability will be involved in the project in the following ways:

a. Our third sector partners will provide us with links to relevant non-statutory organisations to support the case finding activities in Phase 1a and recruitment to the feasibility trial in Phase 2. They will actively facilitate and support these links where necessary, for example, providing introductions to carer forums or leisure activity groups for participants with Learning Disability.
b. We will establish a working group to oversee the development of the intervention materials in Phase I. The Leeds Partnerships NHS Foundation Trust information design service "Easy on the i" will help us develop and evaluate the materials. This group includes service users with Learning Disability and they specialise in producing easy to understand information. People in Action, service users and supporters identified via Tenfold or the Improvement Manager will provide input to the evaluation of the materials, for example, via focus groups facilitated by our third sector partner organisations.
c. We will seek consultation from people with Learning Disabilities and their supporters via People in Action and the umbrella organisation Tenfold to provide input to the design of the interview topic guides for Phase II and the design of participant information sheets, recruitment protocols and consent procedures for Phases 1 and 2. CTRU (AF, LG) have experience of involving hard-to-reach groups in clinical trials and their expertise will enable us to use the expertise of our consultation group and partners most effectively.
d. Project team members, including the project manager, the Research Co-ordinator, Co-I Bryant and CI House will hold regular progress and consultation meetings (approximately every 3 months) with the third-sector partners (and other members of their organisations where appropriate) to ensure their continuous involvement throughout the whole project.
e. Third sector partners will be involved in dissemination activities at appropriate points during the project and afterwards, for example via the Healthy Leeds Partnership Board and Tenfold.

12 PUBLICATION POLICY

Conditions associated with dissemination of research

The HTA stipulates a number of conditions in relation to its funded research which are relevant to this project. They are all contained in the HTA booklet "Instructions to Authors" at http://www.hta.ac.uk/investigators/hta-instructions-to-authors-feb07.pdf. Some notable points are:

- The team are obliged to notify the HTA of any intention to publish the results of HTA-funded work at least 28 days in advance of publication in a journal. This also applies to public oral and poster presentations, hence we are required to advise the NCCHTA 28 days before submission of abstract to organisers of a conference or other event.
- Any dissemination must acknowledge the funding for the project *and* insert a disclaimer in any article or presentation as follows:
  HTA Funding/Publication Acknowledgement: *This project was funded by the NIHR Health Technology Assessment Programme (project number 10/102/03) and will be published in full in*

Health Technology Assessment, Vol. [x], No. [x]. See the HTA Programme website[1] for further project information.

Department of Health Disclaimer: *The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Department of Health*

HTA authorship policy

All persons designated as authors must qualify for authorship, and all those who qualify must be listed. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship. Each author should have participated sufficiently in the work to take public responsibility for the appropriate portions of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article. Authorship should only be based on:

- Substantial contributions to conception and design, or acquisition of data or analysis and interpretation of data
- Drafting the manuscript or revising it critically for important intellectual content
- Final approval of the version to be published

All of these conditions must be met to qualify for authorship. This policy follows the ICMJE Guidelines relating to Authorship and Contributorship and relates to any publication arising from this project.

Authorship and acknowledgement

The success of the project depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated in the project through authorship and by contribution.

Authorship

It is assumed that most publications from this project will follow the medical model, i.e. last author considered to have overall direction of the research and lead author the person who has made the most contribution of intellectual input to the paper. The last author of principle papers would by default be Allan House as CI; the exception being the HTA monograph. Authorship (other than first and last) will then be in descending order of input to the paper. If this is difficult to assess alphabetical order will be used.

The monograph will follow the HTA guidance http://www.hta.ac.uk/investigators/hta-instructions-to-authors-feb07.pdf. The CI (House) will be first author; subsequent authorship and acknowledgements will meet the criteria set by the HTA in section 4. 5 of the booklet "Instructions to Authors"

Co-applicants on the grant and other contributors will not automatically therefore be included as co-authors unless they have contributed to the article as specified above. Opportunities for co-applicants to be involved in the papers will be provided. Co-applicants who do not wish to be involved in writing articles will be included in the acknowledgements. Any disputes relating to authorship will be resolved by the Trial Steering Committee (TSC).

Acknowledgements

The HTA stipulates that where an individual has made a contribution to the manuscript but does not

meet criteria for authorship, their contribution should be recognised in the acknowledgements. Written permission to be acknowledged should have been obtained from such individuals, since readers may infer their endorsement of the data and conclusions.

The CTRU team members not qualifying for authorship should be acknowledged in all publications, as should the HTA (as detailed above). Other key individuals will be included as contributors as appropriate and at the discretion of the Project Management Group (PMG). The Chair and Independent members of the TSC will be acknowledged, but will not qualify for full authorship, in order to maintain their independence.

Relevant NIHR Clinical Research Networks' support should be acknowledged appropriately in publications.

Data source

All quantitative data will be held on the CTRU database in Leeds, including all the health economics data for Phase II. These data must be used for data analyses for all abstracts and publications relating to the relevant questions posed within the protocol. Furthermore, the statistical team at the CTRU must perform all such analyses, other than the Health Economics analysis which will be performed by the Health Economist.

All qualitative data will be held securely at LIHS. These data will be used for all relevant qualitative analyses relating to the questions posed within the protocol. Analyses will be performed by the appropriate members of the research team.

It is recognised that the data or materials relating to the OK-Diabetes project might lead to spin off papers that cannot be anticipated at this point in the project. Authorship and acknowledgements will be considered as and when these papers arise but will also be required to meet the criteria set out here. If any additional analyses outside the remit of the protocol are to be performed, the statistical team at the CTRU should be involved if it involves data held on the CTRU databases.

Data release

To maintain the scientific integrity of the project, data will not be released prior to the first publication of the results of the primary analyses of Phases I or II, either for publication or oral presentation purposes, without the permission of the TSC. The TSC must be consulted prior to release or publication of any data.

Individual collaborators must not publish data concerning their participants which is directly relevant to the questions posed in the study until the main results have been published. Local collaborators may not have access to study data until after publication of the main results.

Processes for the drafting, review and submission of abstracts and manuscripts

The agreed first author is responsible for proposing a provisional authorship list to the Project Working Group (PWG), which will be agreed by the PWG. Once authorship is agreed, the first author is responsible for ensuring all authors meet HTA criteria and acknowledgements are appropriately made.

The first author of manuscripts is responsible for ensuring:

- Timely circulation of all drafts to all co-authors during manuscript development and prior to submission
- Circulation of abstracts and manuscripts to other relevant members of the Project Management Group (PMG) for review at least 15 days prior to the deadline for submission.
- Timely (and appropriate) circulation of reviewers' comments to all co-authors
- Incorporation of comments into subsequent drafts
- Communication with the TSC to include ensuring the TSC receives the final draft prior to

submission.

The first author is responsible for submission to the selected publication and must keep the PWG and all authors informed of the abstract's or manuscript's status. The TSC will be kept informed of rejections and publications as these occur. On publication, the first author should send copies of the abstract or manuscript to the TSC, PMG, Sponsor and to all co-authors and ensure communication with the HTA as outlined below.

Open access requirements

This project must comply with the University of Leeds publication policy (*library.**leeds**.ac.uk/ **university-publications)***. The policy requires authors to upload the full text of all publications to the University Publications Database via Symplectic. These will then be made open access (copyright permitting) via White Rose Research Online. The series name **must** be entered as *Health Technology Assessment* and the publisher is the 'NHS Health Technology Assessment Programme'.

We should select journals which allow open access within 6 months of publication. See http://www.nihr.ac.uk/research/Pages/Research_Open_Access_Policy_Statement.aspx

The project is also required to deposit any research papers that have been accepted for publication in a peer-reviewed journal (or final reports and/or executive summaries) at the earliest opportunity – and in any case within six months - in Europe PubMed Central (Europe PMC).

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Appendix 1: Glossary of Terms

ADL	Activities of Daily Living
BMI	Body Mass Index
BNF	British National Formulation
BP	Blood Pressure
CI	Chief Investigator
CRF	Case Report Form
CTRU	Clinical Trials Research Unit
EQ5D	EuroQol 5D
GCP	Good Clinical Practice
HbA1c	Glycated Haemoglobin
HRQoL	Health-Related Quality of Life
HTA	Health Technology Assessment
LA	Local Authorities
LD	Learning Disability
LIHS	Leeds Institute of Health Sciences
MODY	Maturity Onset Diabetes of the Young
MRC	Medical Research Council
MREC	Multicentre Research Ethics Committee
MSSM	Manualised Supported Self-Management
NHS	National Health Service
NRES	National Research Ethics Service
PHQ9	9-item Physical Health Questionnaire
PIS	Patient Information Sheet
PMG	Project Management Group
PSSRU	Personal Social Services Research Unit
QALYs	Quality Adjusted Life Years
QL	Quality of Life
RCN	Royal College of Nursing
RCT	Randomised Controlled Trial
RUSAE	Related but Unexpected Serious Adverse Event
SAE	Serious Adverse Event
SDSCA	Summary of Diabetes Self-Care Activities
SL	Standard Leaflet
SOP	Standard Operating Procedure
TAU	Treatment as Usual
TMG	Trial Management Group
TSC	Trial Steering Committee
QOF	Quality Outcomes Framework

Appendix 2: Project Management Group

The PMG includes those listed as key contacts and the following Co-applicants:

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