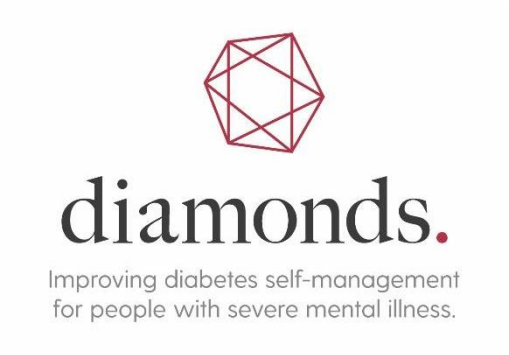

The DIAMONDS Programme

(Diabetes and Mental Illness, Improving Outcomes and Self-management)

RANDOMISED CONTROLLED TRIAL

TRIAL PROTOCOL

UNIVERSITY of York

NHS Bradford District Care NHS Foundation Trust

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Trial Synopsis

Scientific title	DIAMONDS: Diabetes and Mental Illness, Improving Outcomes and Self-management	
Public title	DIAMONDS Randomised Control Trial	
Countries of recruitment	England and Wales	
Health condition studied	Type 2 diabetes and Severe mental illness (schizophrenia, bipolar disorder, schizoaffective disorder, psychosis, severe depression)	
Interventions	**Arm 1**: Intervention – 6 month, 1-to-1, self-management programme with intervention facilitators (DIAMONDS Coaches)	**Arm 2:** Control – Usual care
Key inclusion and exclusion criteria	INCLUSION CRITERIA: ● Patients aged ≥18 years ● Severe mental illness (schizophrenia, bipolar disorder, schizoaffective disorder, psychosis, severe depression) ● Type 2 diabetes EXCLUSION CRITERIA ● Cognitive impairments ● Gestational diabetes ● Type 1 diabetes ● Other types of secondary diabetes, e.g. specific genetic defect ● Lack of capacity ● Current Inpatients	
Trial design	Multi-centre, two-armed, parallel, individually randomised control trial with an internal pilot	
Trial participants	Aged ≥18 years	
Planned sample size	450	
Follow-up duration	6 and 12 months post-randomisation	
Planned trial period	03 October 2022 to 03 May 2025 (18 months recruitment and 12 months follow-up)	

Outcomes	**Primary:** HbA1c at 12 months	**Secondary:** BPRS, PHQ-9, PAID, SDSCA, EQ5D-5L, IPAQ Physical Health, diabetes measures Resource use at 6 and 12 months; HbA1c at 6 months

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0.1	01-11-21	Lucy Atha	Set up document and drafted protocol
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0.3	24-04-22	Jen Brown, Najma Siddiqi, Katherine Jones, Claire Carswell, Pete Coventry	Review comments
0.4	05-05-22	Grace O'Carroll	Review comments
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0.6	06-06-22	Steve Parrott PMT group	Health economics, glossary, full document review
1.0	28-06-22	Grace O'Carroll	Review comments

Contents

1. Introduction

1.1. Plain English summary

People with severe mental illness, such as schizophrenia, bipolar disorder, or severe depression, have poorer physical health and a shorter life expectancy by around 20 years compared with the general population. Higher rates and poorer management of physical long-term conditions such as diabetes and heart disease are partly to blame. There may be several reasons for this, including the individual's mental illness and treatment, challenges to engaging in healthy behaviours (e.g. exercise, healthy eating), and barriers to accessing healthcare and support.

Self-management (which includes taking medications, monitoring symptoms, preventing complications, and leading a healthier lifestyle) is an important part of staying well with a long-term condition. There are many self-management programmes in the NHS to help people with long-term conditions look after themselves, but they often do not address the challenges of people who also have a severe mental illness.

The DIAMONDS research programme aims to overcome this problem by developing and testing a self-management intervention that can specifically help people with diabetes and severe mental illness to be healthier. The intervention has been developed in partnership with people with mental illness and diabetes, their family members/friends, and the healthcare staff who support them. It has been designed to address challenges to self-management, which include poor motivation due to mental illness symptoms and medication; limited support from others for self-management; beliefs about their ability to engage in self-management; and limited knowledge and skills for long-term condition management. The DIAMONDS intervention is a 6-month programme that consists of daily self-management tasks and 1-to-1 meetings with a trained facilitator, who we call a DIAMONDS Coach.

In a previous study, we have confirmed that the DIAMONDS intervention can be delivered and is acceptable to those who are delivering it as well as those receiving the intervention. We have also tested our research processes to confirm that we are able to recruit people to join our research and collect the data we need. In this study, which is phase 4 of the DIAMONDS programme, we will compare two groups of participants to test whether our intervention works. One group will receive the DIAMONDS intervention, the other will not. It will be decided randomly which participant will be in which group. We will take blood samples at the beginning of the study and after 6 and 12 months to see if the intervention helps people look after their diabetes.

1.2. Scientific summary

Diabetes is two to three times more common in people with severe mental illness (SMI) than the general population. Access to clinically and cost-effective health care for people with a long-term condition (LTC), such as diabetes, and SMI is challenging. Self-management interventions in particular, which play a central role in the care of diabetes (and other LTCs), are rarely offered to people with SMI in a way that addresses their particular circumstances. Furthermore, the effectiveness of conventional diabetes self-management programmes in people with SMI is not well understood because they are often excluded from research.

This is a protocol for an individually randomised controlled trial (RCT) to test the effectiveness of a tailored diabetes self-management intervention for people with SMI, called the DIAMONDS intervention. The trial forms part of the DIAMONDS programme and follows work streams exploring

the existing evidence, co-designing the intervention and confirming the feasibility of this RCT. We will recruit 450 participants and randomise them (1:1) to receive either the DIAMONDS intervention or usual care. The intervention is a tailored self-management support intervention that includes 1-to-1 sessions with a DIAMONDS coach over a period of 6 months and a paper-based workbook, which can be supported by use of a digital app. The intervention's role is to increase knowledge and skills for diabetes self-management, provide support to increase physical activity levels and other healthy lifestyle choices, setting meaningful goals, and identify and address barriers to taking medication and sleep issues.

The primary outcome will be HbA1c at 12 months post-randomisation and we will collect outcomes at baseline, 6 months, and 12 months post-randomisation. This trial will also determine the cost-effectiveness of the DIAMONDS intervention.

We will seek input from service users throughout the trial and will disseminate the findings in peer-reviewed outputs as well as knowledge products that are accessible to the general public.

2. Background

People with severe mental illness (SMI; i.e., long-term mental illnesses such as schizophrenia, schizoaffective disorder, bipolar disorder, and severe depression)[1] experience higher rates of physical illness than the general population. Their life expectancy is 15-20 years shorter[2-5] mainly due to the comorbid physical illness.[6-8] Accessing clinically and cost-effective healthcare for individuals with a combination of mental and physical illness is recognised as challenging. Both the conditions and their treatments may interact to increase the disease and treatment burden.[9] Consequent health inequalities are exemplified by the experience of comorbid SMI and diabetes, which is two to three times more common than in the general population,[5,10] and associated with poorer outcomes than for individuals with diabetes alone.[6-8]

Supporting self-management in diabetes (in common with other LTCs) is fundamental to improving clinical outcomes;[11-13] about 99% of diabetes care falls to self-management.[14] Self-management refers to the skills, practices, and behaviours that a person engages in to protect and promote their health. Diabetes self-management activities include: improving diet; physical activity; smoking cessation; monitoring glycaemic control; preventing complications; and treatment adherence.[15,16] 'Self-management education' is key to supporting self-management.[13,17,18] In England, diabetes self-management education programmes are recommended for recently diagnosed persons and their family members or supporters.[13] Such programmes typically include educational and behavioural elements to increase knowledge, skills, and ability for self-management,[19] and target healthy diet, exercise, smoking cessation, appropriate self-monitoring, and treatment adherence.[13,20] Self-management education programmes for the general population with diabetes have been found to be clinically and cost-effective.[14,19,21-24]

For people with SMI and diabetes, self-management support is rarely offered (although reliable data on this are difficult to obtain).[25] Moreover, the effectiveness of diabetes self-management programmes for this population is largely unknown as research typically excludes them.[26-28] SMI is characterised by disturbances of thought, perception, affect and motivation,[29,30] which influences self-efficacy, literacy, lifestyle, behaviour, and family life.[31-34] Diabetes self-management programmes designed for the general population do not address these important barriers.[35-38] The STEPWISE trial tested a theory-based, group structured lifestyle education programme to support weight reduction in people with schizophrenia. While the intervention was neither clinically nor cost-effective, the STEPWISE trial highlights the challenges of improving physical health in people with

schizophrenia. The trial contributes to efforts to maintain momentum in overcoming the unacceptable health inequalities among people with SMI and address further widening of health inequalities in this population.[12]

The DIAMONDS programme aims to develop and evaluate a self-management intervention for people with SMI and diabetes. The goal of the intervention will be to support people to engage in health protective behaviours, improve glycaemic control, and manage mental health comorbidities.

We have developed a 1-to-1 supported self-management intervention that is based on behaviour change theory, principally the theoretical domains framework.[39] This process involved systematically reviewing the literature with a focus on living with SMI and LTCs to identify mechanisms of action that underpin candidate behaviour change techniques (BCTs).[40,41] A BCT is a theory-based strategy that helps an individual change their behaviour to promote better health (e.g. setting goals, taking unhealthy foods out of the house, or planning actions) and mechanisms of action are the processes through which they affect behaviour. Additionally, we conducted in-depth semi-structured interviews to better understand the lived experience of people with SMI and LTCs and their friends, relatives, and carers. Health professionals supporting people with SMI were also interviewed (DIAMONDS Quest; Greater Manchester – West REC: 18/NW/0603; IRAS: 249062). These qualitative data were integrated with the review findings to use in a consensus exercise to identify which mechanisms of action, associated BCTs, and modes of delivery offered the most potential to modify self-management behaviours in people with SMI and LTCs.

We then worked in partnership with people with SMI and diabetes, their family members/friends, and healthcare staff who support people with SMI and diabetes to co-design[42-45] intervention prototypes of the diabetes self-management interventions. We did some preliminary user testing of the prototypes to establish acceptability and functionality of the intervention (DIAMONDS Co-design; Greater Manchester – West REC: 19/NW/0356; IRAS: 264126). A feasibility study using a quasi-experimental design with an embedded mixed-methods process evaluation was then completed (DIAMONDS Feasibility study; Yorkshire & The Humber – Leeds West REC: 21/YH/0059; IRAS: 279019; ISRCTN: 15328700) which helped to inform the design of this RCT and to make modifications to optimise the intervention.

2.1. Aim and Objectives

2.1.1 Aim

To investigate the clinical and cost-effectiveness of the DIAMONDS intervention for people with SMI. This will be compared to usual care.

2.1.2 Objectives

i. To undertake a 12-month internal pilot to obtain robust estimates of recruitment and retention and to confirm trial viability.

ii. To undertake a randomised parallel group comparison to determine the effects of the DIAMONDS intervention on glycated haemoglobin (HbA1c) at 12 months post-randomisation (primary outcome).

iii. To undertake a randomised parallel group comparison to determine the effects of the DIAMONDS intervention on outcomes related to physical health, psychological health and diabetes taken at 6 months and 12 months post-randomisation.

iv. To conduct a detailed economic evaluation to assess the cost-effectiveness of the DIAMONDS intervention for both the within trial period and the longer term.

v. To conduct a process evaluation that will harness data from both qualitative and quantitative sources to address questions about whether the intervention was delivered as intended and how outcomes were produced. Additionally, the process evaluation will aim to identify barriers and enablers to post-trial implementation and scale-up, including whether the intervention can support self-management of other LTCs in people with SMI.

3. Study methods

3.1. The study team

The DIAMONDS Programme is a multi-disciplinary study led by the chief-investigator (Prof Najma Siddiqi) at the Department of Health Sciences, University of York (UoY). The University of York is the Sponsor for the RCT, Bradford District Care NHS Foundation Trust (BDCFT) is the lead trust responsible for the delivery of the work, and the National Institute for Health and Care Research (NIHR) the funder of the work. This RCT is jointly led by a process Evaluation Lead (York) and a senior diabetologist (Southampton), with support from a senior statistician (York). Key Contacts for this trial are listed on page 2.

The study team comprises researchers from the Universities of York, Southampton, Leeds, and Dundee as well as members of NHS Trust Research and Development (R&D) teams (or equivalent) at participating sites. Members of the R&D team will receive adequate training as needed in the use of the outcome measures included in this trial. The R&D teams will be responsible for consent procedures and data collection with the exception of the qualitative interviews for the process evaluation which will be conducted by researchers at UoY.

3.2. Study design

This study is a multi-centre, two-armed, parallel, individually randomised control trial with embedded process and economic evaluations. The trial includes a 12-month internal pilot phase to assess recruitment assumptions and optimise trial processes. The trial has an 18-month recruitment (including 12-month pilot period). Following randomisation, participants will be followed-up for one year with outcome assessments conducted at 6 and 12 months post randomisation.

3.3. Study setting and sites

The study setting will include NHS mental health trusts across England and Wales. General practices will also be used as Participant Identification Centres (PICs) to identify patients who are potentially eligible to take part in the trial. In addition, interested individuals within England and Wales will be able to self-refer to the trial.

3.4. Consideration of the NIHR Include Framework

We have designed our eligibility criteria as well as the recruitment and consent procedures for the DIAMONDS RCT under careful consideration of the NIHR INCLUDE Framework. [46] By its very nature,

the DIAMONDS Programme aims to serve a highly vulnerable at-risk population that is often excluded from other research studies: people with severe mental ill health, with several health problems, who are often experiencing economic and social discrimination, inequality, and disadvantage.

However, we are conscious that within this group, which forms the population that the DIAMONDS Programme looks to serve, there will be under-served subgroups who are not appropriately represented in studies. Our eligibility criteria take an inclusive approach, for example by not specifying an upper age limit, excluding women of childbearing age, or limiting by comorbidities.

Our recruitment and consent procedures were developed in collaboration with DIAMONDS Voice and local NHS mental health Trusts and informed by learning from the DIAMONDS feasibility study. They address some of the barriers to inclusion as identified by the INCLUDE Project, for example:

- Poor trial promotion - the DIAMONDS RCT will be widely promoted in a range of formats using new and existing online and offline networks, Co-developed by DIAMONDS Voice.
- Lack of effective incentives for participation/negative financial impact – on the advice of DIAMONDS Voice we have decided to offer participants a high street shopping voucher to show our appreciation for their participation. To avoid any financial disadvantages for participants, we will reimburse all participation-related costs, including travel, carer expenses, and childcare.
- Poor consent procedures - our consent procedures are based on processes that have previously been shown to be effective in the population of interest. They have been developed with input from DIAMONDS Voice and their appropriateness and acceptability has been confirmed in the DIAMONDS feasibility study.

Nevertheless, we acknowledge that there may be groups we are still not reaching, for example people in full-time employment, people living in remote areas, or those experiencing language barriers. In line with the NIHR INCLUDE Roadmap, we will work with our local NHS partners, key stakeholders, and recruiting Trusts to ensure a dynamic study delivery that will allow us to remove further barriers and increase opportunities for under-served groups as appropriate in the local context. This will be explored within the internal pilot.

3.5. Study population

Inclusion criteria

The target population will be adults (aged 18 years or older) living in the community with SMI (schizophrenia, bipolar disorder, schizoaffective disorder, psychosis, severe depression) **and** type 2 diabetes (insulin and non-insulin treated). The diagnosis of both diabetes and SMI needs to be of at least three months duration and documented in the medical record. Individuals living in supported housing or residential facilities will be eligible.

People living with additional mental and physical comorbidities are eligible as long as there is a diagnosis of both SMI and type 2 diabetes.

Exclusion criteria

People who have cognitive impairments and those with a diagnosis of gestational diabetes, type 1 diabetes, or other types of secondary diabetes will be excluded. We will also exclude people who lack capacity to participate in the trial, guided by the 2005 Mental Capacity Act. Current inpatients

will also not be eligible for inclusion. We will further exclude individuals who present with a diagnosis of anxiety, personality disorder, eating disorders, obsessive-compulsive disorder or any other mental health condition, regardless of severity, that is not included within our definition of SMI as per the inclusion criteria, unless there is also a diagnosis of one of the eligible conditions.

3.6. Recruitment and consent procedures

We will recruit participants using methods successfully deployed in the SCIMITAR, STEPWISE, PRIMROSE trials, and the DIAMONDS feasibility study and use a staged consent procedure. All participant-facing documents were produced in collaboration with DIAMONDS Voice, our service user group that has been an integral part of the DIAMONDS programme for several years. Refinement of the recruiting process will be undertaken during and in response to the internal pilot.

Identification of potential participants from primary care

GP database screening

Primary care sites will act as Participant Identification Centres (PICs) in this trial. No participants will be enrolled into the trial in primary care, i.e. those individuals identified as potentially eligible through primary care will be consented into the trial through secondary care recruiting sites (mental health Trusts). Data collection and delivery of the intervention will be conducted by the secondary care sites.

Working with NIHR Local Clinical Research Networks (CRNs), general practices will be asked to consult their SMI and LTC Quality and Outcomes Framework (QOF) registers to screen for potentially eligible patients. General Practitioners at participating practices will check the lists produced by the database search to confirm eligibility. When a potential participant is identified, the primary care site will provide them (either by post or during the consultation) with a brief study information leaflet and a consent-to-contact (CTC) form. Upon receipt of the completed CTC form, the UoY study team will send a study information pack containing an invitation letter to join the study and a participant information sheet (PIS) to the potential participant. They will receive a follow-up telephone call from an R&D team member a few days later to discuss the study and to arrange a face-to-face meeting with the R&D teams. If the potential participant is willing to join the study, consent will be taken during this meeting.

Primary care referral following annual health check

We will encourage all staff at participating PICs to make people with SMI and type 2 diabetes aware of our trial when they receive their annual primary care health check. A brief study information leaflet and CTC form will be given to interested and potentially eligible patients during their health check. For patients who are receptive to taking part in the trial and have capacity to agree to be contacted during their clinic visit, practice staff will complete and return by post patients' CTC form to the study team who will then initiate the full consent process as above.

Recruitment from secondary care (NHS mental health Trusts)

A substantial proportion of people with SMI will be under the care of a community mental health team (CMHT) or another service within secondary care. We will develop locally applicable procedures to identify potentially eligible patients, which may include one or a combination of caseload screening, database searches, and/or patient lists provided by Trust pharmacies, as appropriate and available. Patients identified as potentially suitable for the DIAMONDS trial will

receive a brief study information leaflet. Several days later, a member of the R&D team will get back in touch with the potential participant and send through the full PIS and invitation letter. The consent process will then continue as above. To ensure the study team at the UoY has permission to contact participants with trial-related matters, participants identified through secondary care will be asked to complete a contact details form and give consent for their details to be shared.

Identification of potential participants from existing research cohorts

We will re-contact individuals who have previously taken part in related research projects conducted within our research group at UoY and who have given permission to be approached about future opportunities to participate in research. These contacts may stem, for example, from the DIAMONDS sub-studies DIAMONDS Quest and DIAMONDS Co-design, the related studies EMERALD and DAWN-SMI.

Individuals identified via this route, will receive a short PIS in the post followed up with a phone call a few days later by the UoY study team. If the individual expresses an interest in taking part in the DIAMONDS RCT, their nearest participating Trust will contact them to initiate the consent process described above. Eligibility will be confirmed before consent is taken.

Individuals who participated in the DIAMONDS feasibility study will not be eligible for participation in this RCT.

Participant self-referral

We will also aim to approach people living with SMI and diabetes who do not engage well with services, and therefore may not respond to an invitation from their GP or mental health care provider. Similarly, not all potentially eligible patients will have an opportunity to discuss participation in the DIAMONDS RCT with their healthcare provider during the trial recruitment period.

We will therefore aim to recruit from relevant local third sector organisations and service user groups (e.g. MIND, https://www.yorkmind.org.uk/; Touchstone, https://www.touchstonesupport.org.uk/, Volition, http://www.volition.org.uk/about/), which are based in the same locations as practices and mental health Trusts recruiting for the study. Posters and flyers advertising the study will be placed in third sector organisation venues, general practice waiting rooms, and mental health Trust clinics (and other appropriate settings); and/or on practice /trust/organisation websites, and social media channels. These will be limited to organisations and services taking part in the study to recruit participants. The trial will also be promoted via UoY social media and other web channels. People, who having seen this information, are interested in taking part in the trial, will be directed to the person in the organisation/service supporting the study, or the DIAMONDS study team. As above, they will be provided with a brief study information leaflet and will be asked to complete the CTC form and return it to the study team.

Potential participants who have self-referred, will also be contacted by their nearest participating Trust to arrange a consent and baseline appointment. At this stage, the secondary care teams will confirm the individual's eligibility by ascertaining their type 2 diabetes and SMI diagnosis.

At their consent and baseline appointment, all potential participants regardless of recruitment route will have a further opportunity to clarify any points they did not understand and ask any questions. A full verbal explanation will be given by the researcher taking consent who will be an appropriately trained member of the study team and cover all elements specified in the PIS. It will be emphasised

that the participant may withdraw their consent to participate at any time and without having to provide a reason and without it affecting their usual care or benefits to which they are entitled. The participant will also be informed that by consenting, they agree to their GP being made aware of their participation in the trial. Written informed consent will be obtained with both the participant and the researcher signing and dating the consent forms prior to randomisation. A copy of the completed and signed consent form will be given to the participant.

There may be circumstances in which verbal consent will be taken over the phone or via a video conferencing platform. In those instances, the researcher will read out a verbal consent script and then the consent form, recording the prospective participant's answers. Verbal consent forms will be signed and dated by the researcher and a copy sent to the participant for their records.

3.7. Sample size

The sample size calculation was based on detecting a clinically meaningful difference of 5.5 mmol/mol (0.5%) in HbA1c at 12 months. This difference was selected based on data from trials of diabetes self-management in the general diabetes population[47,48] and NICE guideline on type 2 diabetes management.[13] Based on the variation observed in HbA1c in a Clinical Practice Research Datalink (CPRD) population study,[49] we assumed a standard deviation of 15.3 mmol/mol. Based on attrition rates in previous severe mental illness trials,[50,51] we expect approximately 20% attrition. In the intervention arm, a DIAMONDS Coach will deliver the intervention to multiple participants, and therefore the outcomes of participants with the same coach may be correlated. Although only a small clustering effect is expected, this provides a more conservative sample size estimate. The sample size was therefore adjusted for clustering in the intervention arm.

For approximately 90% power, at the 5% significance level, assuming an average cluster size of 10-12 participants per DIAMONDS coach with an intraclass correlation (ICC) of 0.02 in the intervention arm, and adjusting for 20% attrition, we estimate we will need to randomise 450 participants, with 225 per treatment group.

3.8. Baseline assessment

Prior to randomisation, all consenting patients will undergo baseline assessment, including a questionnaire and clinical assessments. The baseline questionnaire will include patient demographics, and questionnaires related to the secondary outcomes. An appropriately trained member of the R&D team will carry out baseline assessments. We will also ascertain that those individuals carrying out physical measurements (including blood taking) are appropriately trained, and that correctly maintained and calibrated equipment is used. Blood sample collection, processing, and analysis procedures are explained below.

In addition, all participants will be offered a wrist-worn accelerometer at their baseline appointment to be worn for a period of seven days. Details about the device and the deployment and data collection procedures are described below.

3.9. Randomisation

Following completion of all baseline measures, with the exception of the accelerometer wear-period that will continue for seven days, the R&D team will arrange randomisation. Consenting participants will be randomised on a 1:1 basis to either the DIAMONDS intervention (n=225) or the usual care

group (n=225) using computer generated permuted blocks of random sizes. Randomisation will be carried out by York Trials Unit (YTU; UK Clinical Research Collaboration Registration ID Number: 40) independently of the R&D team using a secure, online randomisation service to ensure allocation concealment. The online system will require confirmation of patient eligibility prior to randomisation being carried out. Participants will be informed of their group allocation in person during their baseline appointment. They will then be informed of next steps depending on which group they have been randomised to.

After randomisation, a letter will be sent to the participant's GP to advise them of their patient's participation with a request for this to be recorded in the participant's medical record. Participation in the DIAMONDS RCT and group allocation will also be recorded in patient records held within secondary care at the recruiting Trust.

The DIAMONDS Programme Manager and Trial Coordinators will be un-blinded to allocation in order to facilitate contact between randomised participants and their designated DIAMONDS Coach, if required. Following randomisation, the participating site will contact DIAMONDS Coaches to advise them to approach participants randomised to the intervention group to arrange the first intervention session.

3.10. Blinding

With the exception of the Programme Manager and Trial Coordinators (see above), efforts will be made to ensure the R&D team, including those members of the team involved in data collection, are blinded to participants' group allocation. Participants will be instructed on whom they can discuss their allocation with, and from whom they should withhold this information. Should the participant inadvertently reveal their allocation to an outcome assessor, or the assessor becomes un-blinded for any reason, this will be recorded in the outcome assessment CRF at the relevant time. Baseline assessments are conducted prior to randomisation. Due to the nature of the comparison between the DIAMONDS intervention and treatment as usual, neither participants themselves nor the intervention facilitators (DIAMONDS Coaches) will be blinded. It will also not be feasible to blind the trial statisticians and health economists. The DIAMONDS Programme Manager will not be involved in analysis of data.

There is a risk of members of the study team inadvertently finding out a participant's group allocation during follow-up data collection. In those instances, we will have procedures in place to report un-blinding of data collection and will work with the R&D teams to minimise the risk of this happening repeatedly.

3.11. Intervention arm (DIAMONDS intervention)

The intervention content is reported in line with the TiDieR checklist.[52]

Rationale and goals of the DIAMONDS intervention

The DIAMONDS intervention is a tailored self-management support intervention to help people with type 2 diabetes and SMI self-manage diabetes through:

- increasing knowledge and skills for diabetes self-management
- providing support to increase their physical activity levels and make healthier food choices

- identifying and addressing sleep difficulties, barriers to taking medications, and other key problem areas as identified by the participant with support from their Coach
- supporting participants to manage their diabetes within the context of fluctuating and low mood

Materials and mode of delivery

The intervention will be delivered by a trained facilitator (the 'DIAMONDS Coach'), over a period of six months, using a combination of individual sessions and daily use of a paper-based workbook (the 'DIAMONDS Workbook') which can be supported by daily use of a digital app ('Change One Thing'; optional) (see Figure 1 and details below).

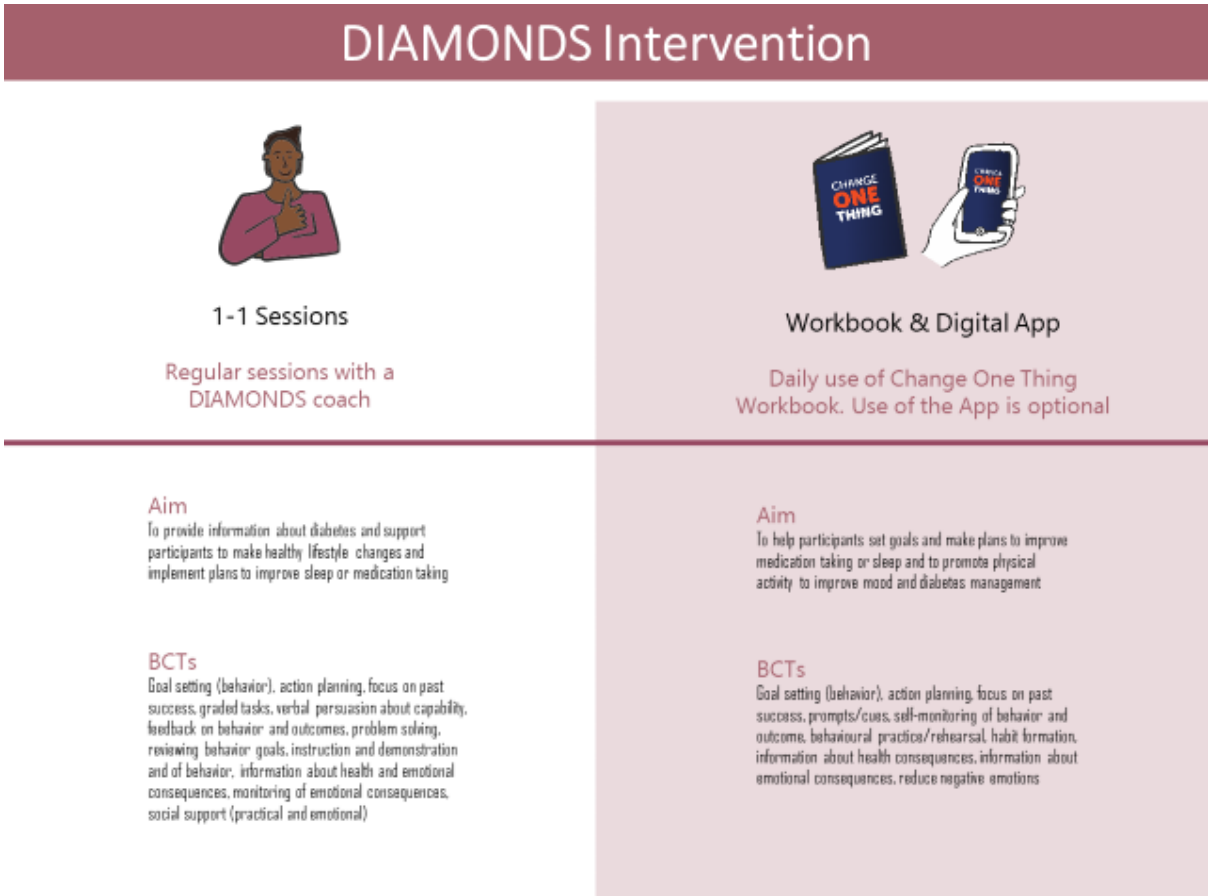

Figure 1: The DIAMONDS Intervention.

1-to-1 sessions

Participants will be offered individual sessions over a six-month period with a DIAMONDS Coach. Within the six-month period, the Coach and participant will have the flexibility to meet as often as they both would like. Coaches will be encouraged to accommodate participant preference for session frequency; however, Coaches will need to manage their own workload and capacity. Based on findings from our feasibility study, we anticipate that intervention sessions will take place approximately every ten days, though a higher or lower frequency of sessions is possible.

The six-month intervention delivery period will start at the point of randomisation. The first session will occur as soon as possible after randomisation, ideally within 14 calendar days. Coaches will be asked to contact their participants within three working days after randomisation to arrange the first session.

To ensure on-time delivery of the trial, we will not "stop the clock" to allow for periods of absence due to illness, holidays, or other reasons on behalf of either the participant or the Coach. The intervention delivery window will end six calendar months after randomisation. This will be communicated clearly to the participant from the start.

We expect that the first session will last between 60 and 90 minutes and follow-up sessions will each last between 30 and 60 minutes depending on the needs and preferences of the participant. Where possible, all sessions will be delivered face-to-face; however, the intervention has been designed to allow remote delivery. As far as possible, Coaches will be encouraged to accommodate participants' preferred mode of delivery. There will be instances where face-to-face delivery is not possible, for example due to geographical distance between Coach and participant. The University of York (Sponsor) and the lead trust will work together to develop a lone worker protocol to ensure the safety of the DIAMONDS Coach.

Ideally, participants will work with the same Coach for the duration of the six-month intervention delivery phase. However, during times of absence or unavailability Coaches will provide cover for one another. Participants will be made aware of this and, wherever possible, Coach changes will be discussed with the participant in advance.

The aims of these 1-to-1 sessions are to provide information about diabetes, support participants to increase physical activity levels and make other healthy lifestyle changes, and to set goals and implement plans to improve sleep, medication taking, and/or other areas the participant wishes to focus on as agreed with their Coach. The participant will continue to engage with the intervention between these sessions. This process will be supported by the DIAMONDS Workbook and the Change One Thing app. Use of the app is optional; DIAMONDS Coaches will encourage participants to use the app and will be trained to facilitate this. The DIAMONDS Coach will use the DIAMONDS Workbook and the digital app ('Change One Thing') to deliver a combination of behaviour change techniques. As part of their role, they will support the participant to prepare the workbook and set-up the app in a 1-to-1 session and provide guidance about how to use these resources between sessions.

For the purposes of data collection, the intervention endpoint will be six months post-randomisation regardless of the number of sessions attended by the participant. Session content will not be sequential but will instead be tailored to the participant's needs; "missed" sessions will not necessarily mean that the participant misses out on intervention content. From the outset, participants will be informed that sessions will stop six months post-randomisation. During the last month (or earlier if the participant wishes to stop receiving the intervention before the end of the six months), the coach will support participants to set longer-term goals and action plans for self-management and help them to access appropriate support to implement these. Participants will be able to continue engaging with intervention content after follow-up data are collected through continued use of the app and/or workbook.

The DIAMONDS Workbook

The DIAMONDS workbook will be used by the DIAMONDS Coach and participant together in the sessions, and by the participant in between sessions. The workbook is divided into five sections:

1. Information about diabetes and diabetes self-management, delivered in discrete topics (e.g. What is diabetes?, checking blood sugar, healthy eating, getting active, taking medication, preventing complications, getting help).
2. A physical activity goal setting record sheet for the DIAMONDS Coach and participant to use each session.
3. A paper-based version of the Change One Thing app so that participants who do not wish to or who are not able to use the app are still able to access these elements of the intervention.
4. Personalised information about who the participant should contact if they experience problems with their mental health or diabetes, who in their social network can provide social support, and details of local services available to them to support diabetes self-management (e.g. peer support groups, exercise classes). This will be completed by the DIAMONDS Coach with the participant in the first session and updated throughout the intervention delivery period as needed.
5. Information about the Change One Thing app and how to use it.

Following the follow-up data collection at six months post-randomisation, participants can continue to use the workbook to support their self-management. The Coach will discuss this with them in the final session and offer to dispose of the workbook should they not wish to continue using it.

Change One Thing – Digital app

'Change One Thing' is a digital app for use on mobile devices. It has been co-designed by service users and carers during the DIAMONDS Co-design study and refined subsequently with input from DIAMONDS Voice. Participants will be encouraged to use the app as part of the intervention and will receive support and encouragement for this from the DIAMONDS Coach during 1-to1 sessions. Participants will be encouraged to download the app onto their own mobile device (smartphone or tablet). In the first session, barriers to using the app will be explored (e.g. accessibility, connectivity, device) to determine whether the participant can use the app. If participants decline to use the app in the first session, the Coach will repeat the offer to use the app, and encourage and support participants to do so, in later sessions.

Change One Thing aims to support participants to set one goal at a time with the DIAMONDS Coach and develop an associated action plan, with the aim to make achievable changes through the delivery of daily prompts, making physical activity suggestions based on participant preference, mood and the weather, providing information about the consequences of self-management, and enabling self-monitoring. Following follow-up data collection at six months post-randomisation, participants can continue to use the app to support their self-management. The Coach will discuss this with them in the final session, and support participants to remove the app should they not wish to continue using it.

The app was created by a digital development agency with expertise in delivering health related technologies. It is available for iOS (Apple) and Android through the App Store and Google Play, respectively. Participants will be assigned a PIN generated by the content management system (CMS) which will allow them to access the app once downloaded. Only individuals with a PIN can use the app.

Intervention facilitators: DIAMONDS Coaches

DIAMONDS Coaches will be equivalent to band 4 Agenda for Change NHS workers recruited from a wide range of professional backgrounds (including but not limited to dieticians, health trainers,

physiotherapists, nurses, care coordinators). Current or recent experience of working with people with SMI or substantive experience delivering behaviour-change interventions will be essential to be trained as a Coach. The Coaches will undertake a bespoke training course designed and facilitated by members of the Leicester Diabetes Centre with support from the study team. The training will include content on diabetes, self-management, and SMI, as well as instructions on using the DIAMONDS intervention (both paper-based and digital). DIAMONDS Coaches will also receive training on the intervention philosophy and key behaviours and activities that need to be included in the 1-to-1 sessions as well as study processes such as withdrawal and adverse event reporting. To support Coaches throughout the intervention delivery phase of the trial, LDC will provide ongoing mentorship as well as encourage peer-to-peer support between Coaches.

Access to standard care will continue as usual for participants in the intervention arm outside of the trial.

3.12. Control arm

Participants in the control group will access usual care for people with SMI and diabetes (including the offer of NICE-recommended generic diabetes self-management education programmes). This will include primary care health checks for SMI and diabetes along with community based mental health care through CMHTs. We will provide details of commissioned generic diabetes self-management education programmes in the area to all participants and their GPs. Participants in the control arm will be eligible to self-enrol in these existing programmes. Participants randomised to the control arm will be signposted to these services immediately following randomisation.

3.13. Outcomes and data collection

Data collection will be carried out by appropriately trained members of the R&D team in each participating trust using calibrated trust equipment following standard trust procedures. All data will be recorded on standardised, machine-readable forms. Completed forms will be returned to the study team by post. The UoY study team will assign a unique ID code to each participant. If a participant is unable to attend a clinic appointment for their data collection, the R&D team will attempt to collect the data by post or over the phone.

The main aim of the trial is to test the clinical effectiveness of the intervention. Below is a list of proposed primary and secondary outcomes to be collected (see also *Table 1: Outcomes assessed at baseline and follow-up.*).

Primary outcome

The primary outcome of the DIAMONDS programme is the difference in glycated haemoglobin (HbA1c) between the treatment groups at 12 months post-randomisation. To avoid the inadvertent introduction of differences in measurements of HbA1c through the use of several local laboratories, we will arrange the use of one central United Kingdom Accreditation Service (UKAS) registered laboratory for all blood sample analyses. Blood samples will be sent to the lab from the participating sites. The lab will return test results (recorded as mmol/mol and %) to the study team at the UoY by post.

Participants who decline a blood test will be asked to consent to sharing the results of their most recent routine blood test results held in primary or secondary care records. HbA1c represents average blood glucose over a six to eight-week period. We will only use routine test results that have been reported between six weeks before to six weeks after the end of the scheduled follow-up date.

We anticipate that the DIAMONDS intervention will lead to a number of behaviour/lifestyle changes, which directly or indirectly affect blood glucose levels. Glucose homeostasis is associated with cardio- and cerebrovascular events, microvascular complications and mortality in diabetes. We have, therefore, chosen a measure of glucose control, HbA1c, as our primary outcome and included a number of other important parameters that influence morbidity and mortality as secondary outcomes.

Secondary outcomes

Physical health

Cholesterol: Measured as part of a biochemical lipid profile (blood test) taken at the same time as the blood for the HbA1c measurement. Total cholesterol, HDL cholesterol, and triglycerides (all measured in mmol/L) will be recorded. LDL cholesterol will also be calculated.

Haemoglobin: Blood test taken at the same time as blood for HbA1c measurements and lipid profile. Haemoglobin will be recorded in g/L. All blood tests will be conducted at the same central laboratory.

We will share participants' blood results with their GP via post marked 'confidential'.

Body mass index (BMI): Calculated using weight (kg) and height (metres) measurements using the following formula: $\frac{weight\ (kg)}{height\ (metres)^2}$

Waist circumference: Measured following standard trust procedures and recorded in cm.

Blood pressure: Systolic and diastolic blood pressure measured following standard trust procedure and recorded in mmHg.

Smoking status: Assessed through participant self-report: yes/no/never

Urinary albumin to creatinine ratio: Will be extracted from patients' medical records as a measure of diabetic nephropathy.

Physical Activity: Physical activity will be measured using the International Physical Activity Questionnaire (IPAQ).[53] This instrument is a 7-item self-reported (short form) assessing physical activity in the last 7 days. Results will be reported in categories of activity levels (low, moderate, high).

In addition, we will provide all participants with wearable wrist accelerometers to obtain an objective measure of physical activity. Accelerometers will be given to participants at their baseline assessment and again at the six months follow-up time point, where they will be asked to wear the device continually for seven days. At the end of the seven-day period, they will be asked to return the device to the UoY team; this will be facilitated by the study team as needed. The UoY team will carry out all data download and device set-up. The R&D teams will receive instructions on how to activate the devices to start data collection.

Acceptability of wrist-worn accelerometers in this population has been confirmed in the STEPWISE study and the DIAMONDS feasibility study.

We will convert accelerometery data into activity profiles to assess time spent (a) in a sedentary state, (b) doing mild activity, or (c) doing moderate (or high) intensity activity.

Psychological health measures

Psychiatric symptoms: Assessed using the Brief Psychiatric Rating Scale (BPRS).[54] The BPRS assesses the level of 18 symptom constructs such as hostility, suspiciousness, hallucination, and grandiosity. Each symptom construct ranges from 1 (not present) to 7 (extremely severe).

Depressive symptoms: Assessed using the Patient Health Questionnaire-9 (PHQ-9).[55] The questionnaire comprises nine items which are individually scored as 0 (not at all) to 3 (nearly every day) and then added to provide an overall score. The lower the overall score, the lower the severity of depression.

Diabetes measures

Diabetes distress: Assessed using the Problem Areas in Diabetes (PAID) scale, a validated self-report measure of diabetes distress.[56] Each of the questionnaire's 20 items are measured on a five-point scale from 0 (not a problem) to 4 (a serious problem). These scores are summed and multiplied by 1.25 to generate a total score out of 100.

Summary of diabetes self-care activities: Assessed using the Summary of Diabetes Self-Care Activities Measure (SDSCA).[57] This tool contains 11 items, which measure the frequency of performing diabetes self-care activities over the last seven days. The respondent marks the number of days on which the indicated behaviour was performed using an eight-point Likert scale. The first ten items are summed for a total score. Item 11 focuses on smoking habits and assesses the average number of cigarettes smoked per day.

Insulin use: Assessed through participant self-report (yes/no).

Diabetes complications: Extracted from medical records

- Microvascular: Retinopathy, Neuropathy, Nephropathy
- Macrovascular: Myocardial infarction, Peripheral vascular disease, Stroke and Amputation, foot ulcers

Quality of Life

Health-related quality of life: Assessed using the EQ-5D-5L, a validated self-report measure.[58] This generic, validated, patient-reported outcome measure has five health domains (mobility; self-care; usual activities; pain/discomfort; and anxiety/depression) with five response options for each domain (no problems, slight problems, moderate problems, severe problems, and extreme problems). Responses are coded as single-digit numbers expressing the severity level selected in each dimension. In addition, it has a health status visual analogue scale (VAS) that measures self-rated health anchored at 0 ('the worst health you can imagine') and 100 ('the best health you can imagine').

Health resource use

A bespoke health resource use questionnaire that has been tested in the feasibility study and refined in line with feedback received will be used to collect participants' use of primary care, secondary care and community-based services over a six-month period.

Mechanisms of Action

We will quantitatively collect information about the mechanisms of action (MoAs) used in the DIAMONDS intervention. The 'Change One Thing' app has built-in monthly reviews of MoAs that participants will work through with their DIAMONDS Coach at their 1-to-1 sessions. In addition, we will use a set of self-report process measures at baseline and follow-up.

Table 1: Outcomes assessed at baseline and follow-up.

		Baseline	6 months	12 months
Demographics				
Age	Self-report	x	-	-
Sex	Self-report	x	-	-
Ethnicity	Self-report	x	-	-
Index of Multiple Deprivation	Determined by study team based on participant's postcode	x	-	-
Type of SMI	Medical records	x	-	-
Date diagnosed with SMI	Medical records	x	-	-
Date diagnosed with diabetes	Medical records	x	-	-
Physical Health				
Height	Measured by study team	x	x	x
Weight	Measured by study team	x	x	x
BMI (calculated from height and weight)	Calculated by study team	x	x	x
Waist circumference	Measured by study team	x	x	x
Blood pressure	Measured by study team	x	x	x
HbA1c	Measured by study team	x	x	x
Total and HDL cholesterol	Measured by study team	x	x	x
Haemoglobin	Measured by study team	x	x	x
Psychological health				
Brief Psychiatric Rating Scale (BPRS)	Self-report	x	x	x
Patient Health Questionnaire-9 (PHQ-9)	Self-report	x	x	x
Diabetes measures				
Diabetes distress (PAID)	Self-report	x	x	x
Summary of Diabetes Self-Care Activities	Self-report	x	x	x
Smoking status	Self-report	x	x	x

Physical activity (IPAQ)	Self-report	x	x	x
Diabetes microvascular and macrovascular complications	Medical records	x	x	x
Health economic outcomes				
Health-related quality of life (EQ-5D-5L)	Self-report	x	x	x
Health resource use	Self-report	x	x	x
Process evaluation measures				
Mechanisms of Action	Self-report	x	x	x

Trial processes

The main purpose of the trial is to detect clinically meaningful differences in the outcome measures. We will collect data at baseline, six months post-randomisation, and 12 months post-randomisation.

3.14. Analyses

Internal pilot analysis

The recruitment rate and 95% confidence interval (CI) will be estimated from the data collected. A CONSORT diagram will be produced to show the flow of participants through the study and the following outcomes calculated: number of eligible patients; proportion of eligible patients approached for consent; proportion of eligible patients not approached and reasons why; proportion of patients approached who provide consent; proportion of patients approached who do not provide consent; proportion of patients providing consent who are randomised; proportion of patients randomised who do not receive the randomly allocated treatment; proportion of patients dropping out between randomisation and follow-up.

Data will be summarised on the reasons why eligible patients were not approached, reasons for patients declining to participate in the study; reasons why randomised patients did not receive their allocated treatment and reasons for dropout, if available.

Results will be compared against the study's recruitment assumptions and progression targets, and continuation of the trial or relevant modifications will be decided by the Steering Committee and the funding body.

Progression from the pilot phase to the main trial will depend on satisfying pre-specified targets at 12 months from the start of the trial:

	Green	Amber	Red
a) Average number of participants per site per month	2 participant per month	1.3 to <2 participant per month	<1.3 participant per month

b) Recruitment of sites	15 sites	10 to 14 sites	<10 sites
c) Completeness of outcome (HbA1c) data at 6-months	80% of participants with complete outcome	65% to <80% of participants with complete outcome	<65% of participants with complete outcome

The actions taken for the progression criteria are outlined below:

- Green: continue the trial.
- Amber: review procedures to identify underlying problems, and put in place strategies to address these, review after an interval and terminate the trial if recruitment trajectory does not indicate that full recruitment will occur within scheduled recruitment period.
- Red: terminate the trial unless we can confidently identify successful strategies or rapidly resolve the problem.

Quantitative Data Analysis / Statistical analysis

Full analyses will be detailed in a statistical analysis plan (SAP), which will be finalised prior to the end of data collection. Statistical analyses will be on intention to treat (ITT) basis with patients being analysed in the groups to which they were randomised. Statistical significance will be at the 5% level (unless otherwise stated in the SAP), and analyses will be conducted in the latest available version of Stata or similar statistical software. This trial will be reported according to the CONSORT guidelines for clinical trials (Consolidated Standards of Reporting Trials, 2010), and the flow of participants through the trial will be detailed in a CONSORT flow diagram.

Baseline characteristics will be reported descriptively by treatment group. Continuous data will be summarised as means, standard deviations, medians and ranges, and categorical data will be summarised as frequencies and percentages. No formal statistical comparisons of baseline data will be undertaken. Data will be visually inspected and any imbalance reported.

Primary outcome

The primary outcome, HbA1c at 12-month post-randomisation, will be analysed using a mixed effects regression analysis, with HbA1c scores at 6- and 12-months follow-up as the dependent variable, adjusting for baseline HbA1c scores, randomised treatment group, time and a treatment group-by-time interaction, and other important covariates will be included as fixed effects. Variations in outcomes between facilitators will be investigated by including DIAMONDS coach as a random effect in the primary analysis model, nested within treatment arm.[59] The correlation of observations within participants over time will be modelled using participant as a random effect. Different covariance patterns for the repeated measurements will be explored and the most appropriate pattern will be used for the final model. The estimated treatment group difference at 12 months will be reported as the primary endpoint with the associated 95% confidence interval and p-value.

Sensitivity analyses

The amount of missing data will be reported for each randomised arm, and we will also compare the baseline characteristics of participants who are included in the primary analysis to ensure that any attrition has not produced any imbalance in the groups in important covariates. The amount of

missing data will be mitigated by including all data in the primary analysis model, which allows the inclusion of any patient with complete baseline data and valid outcome data at one or more follow-up points. We will explore the extent and pattern of missing data and, if appropriate, will undertake multiple imputation to assess the impact of missing data on treatment effect estimates.

Complier Average Causal Effect (CACE) analyses will be performed for the primary outcome to assess the impact of compliance on treatment estimates.

Subgroup analyses

A subgroup analysis will be performed to explore any differential treatment effects for those with good and those with suboptimal diabetes control at baseline.[49] We will also conduct exploratory subgroup analysis by ethnicity and by insulin use status. The results of any subgroup analysis will be treated cautiously, detailed in advance in the SAP, and include hypothesised direction of effect, in line with best practice.[60]

Secondary outcomes

Secondary outcomes relating to participant's physical health, psychological health, and diabetes measures will be analysed using mixed effects regression analysis for continuous outcomes, and logistic mixed models for categorical outcomes. Models will include assessments at all available time-points and will provide an overall treatment effect over 12 months, as well as estimates at individual time-points (6 and 12 months), reported as estimates and 95% confidence intervals. Different covariance patterns for the repeated measurements will be explored, and the most appropriate pattern will be used for the final model.

Accelerometer data will be collected at baseline and 6-months post-randomisation. Data will be analysed using the R-package GGIR,[61] which performs signal processing of the raw data, including: auto-calibration, detection of abnormal values, detection of non-wear, and calculation of the average magnitude of dynamic acceleration (Euclidean norm minus one g [ENMO]). Files will then be exported to Stata or similar statistical software for further analysis. Descriptive statistics will be reported for each treatment group at each time point (baseline and 6 months) and differences between treatment groups will be reported, adjusted for baseline.

Process Evaluation

The process evaluation will draw on a mixed-methods approach, harnessing data from both qualitative and quantitative sources to address questions about whether the intervention was delivered as intended (i.e. fidelity) and how outcomes were produced (i.e. mechanisms of action). Additionally, the process evaluation will aim to identify contextual and service level barriers and enablers to post-trial implementation and scale-up, including whether the intervention can support self-management of other LTCs in people with SMI. Drawing on best practice methodology for process evaluations[62] we will identify and assess key dimensions related to what intervention activity and content was delivered and how.

Fidelity assessment

In accordance with the guidance set out by Bellg (2004)[63], the Intervention Fidelity (IF) framework for the RCT will measure: i adherence (whether the content of the intervention sessions was delivered as it was designed, including BCTs); ii quality of delivery of intervention sessions [BCTs and the manner/behaviour (both prescribed and proscribed) in which the coach delivers the programme]; iii duration (mean, SD, and range) of the DIAMONDS sessions (have the sessions been

delivered within the estimated time); and iv participant responsiveness to the DIAMONDS intervention (was the information understood and 'received' by participants and did they acquire and enact the anticipated skills). This IF framework was determined and refined through discussions with the study team and findings from the feasibility study.

To enhance fidelity, coaches will be trained in the intervention and supported via ongoing mentorship to deliver the intervention (see section 3.11 for details about Coach training and mentorship). A training handbook and a Coach manual have also been developed to help Coaches deliver the intervention as intended. These manuals and the training cover key aspects including the philosophy underpinning DIAMONDS, coach behaviours, facilitation skills, and behaviour change techniques (BCTs) used to deliver DIAMONDS. The IF assessment tools and procedures were developed and tested throughout the feasibility study. The training handbook and Coach manual, plus the IF assessment tools, were refined after the feasibility study alongside one another, to ensure that the key concepts aligned and they were fit for purpose for this RCT.

Quantitative analysis

Quantitative data will be extracted from Coach session logs, the Change One Thing app content management system, and the fidelity assessments to descriptively summarise:

- Session duration: mean, SD, and range
- Number of sessions delivered: mean, SD
- Mode of delivery (remote, phone, in person): frequencies/percentages
- List of content areas with number (%) participants who discussed each content area
- Average duration a participant stayed with the same action plan/content area
- Average number of content areas covered during total intervention period and workbook and/or Change One Thing app

Adherence, duration, and quality of DIAMONDS sessions

Remote observations (e.g. audio recording of sessions) will be used to assess a sample (up to 10%) of the one-to-one sessions delivered by Coaches. Each Coach will be assessed and each type of session (First, Core or Final) will be assessed at least once. These assessments will be carried out by observers trained in the use of the IF tools to assess the content, duration, Coach behaviours and BCTs delivered. Duration of the intervention sessions will be recorded. The observers will code the quality of delivery by measuring the degree of content delivered, Coach behaviours (both prescribed and proscribed) and facilitation skills. The presence or absence of these intended intervention components will be recorded utilising the IF tools. Fidelity will be quantified by assessing the proportion of presence of pre-specified content (i.e. % planned components/coded components). Where possible, inter-rater reliability of the IF assessors will be assessed using Cohen's Kappa or percentage agreement by prevalence adjusted bias adjusted kappa (PABAK).[64]

Qualitative components will focus on exploring how participants received the intervention and on how mechanisms of impact produced intended or unintended effects. Mechanisms include participant responses to and interactions with the intervention to understand how the intervention produced behaviour change over the short to medium term. We will also evaluate the extent to which MoAs[40] operated as mediators along the pathway to intervention effects. We will consider how contextual factors external to the intervention might potentially moderate delivery of the intervention and possibly moderate outcomes in different settings.

Semi-structured interviews structured around the MoA framework will be conducted with a sample of study (patient) participants and their (informal) caregivers. A combination of focus groups (online or face-to-face) and semi-structured telephone interviews will be used to collect data about the experiences of DIAMONDS Coaches.

Approximately 20-25 interviews will be conducted with patient participants. Patient participants will be purposively sampled along characteristics likely to affect implementation of the intervention (e.g. number of sessions completed, recruitment site, gender, age, socio-economic background, and type of SMI).

We will aim to interview a comparable number of informal caregivers. As in our feasibility study (DIAMONDS Feasibility study; Yorkshire & The Humber – Leeds West REC: 21/YH/0059; IRAS: 279019), informal caregivers are defined as unpaid carers who are not subject to working regulations and provide support to a dependent person who they have a social relationship with, such as a spouse, other relative, neighbour, friend or other non-kin. Care includes support with household chores or other practical errands, transport to doctors or social visits, social companionship, emotional guidance, or help with arranging professional care.[65]

The PIS will inform participants that they may be invited to an interview to give their feedback about the DIAMONDS Intervention. All potential interview participants, i.e. patient participants randomised to the intervention group, carers, and Coaches, will be approached with a separate PIS and consent form specifically for the qualitative interview component of this trial. Patient participants will be asked to identify an informal caregiver. Where relevant, patient participants will be given a carer CTC form for the carer to share their contact details and give permission to the study team to contact them to arrange an interview. If the participant is unable to identify a caregiver, the following probes will be used:

- Someone who supports you with managing your medication
- Someone who supports you with organising or attending appointments
- Someone who supports you with daily activities such as cooking, cleaning, shopping

On receipt of a carer CTC form, the study team will post a study information pack (containing an invitation letter, participant information sheet, consent form and freepost envelope). Interested caregivers will be invited to complete and return the consent form to the study team or to contact the study team by email or telephone. A member of the study team will then contact the informal caregiver to discuss their participation.

DIAMONDS Coaches will also be asked to identify and discuss the involvement of informal caregivers with the participants. Where informal caregivers may be interested in participating in the study, the Coach will invite the patient participant to complete the carer CTC form and return this to the study team, or will obtain their verbal 'permission to contact' for the study team to post the informal caregiver a study information pack and/or to contact them to discuss the study. Where an informal caregiver has completed and returned a written consent form, they will be provided with a copy.

Participating Trusts will be responsible for approaching and obtaining consent from patient participants and their carers for participation in the qualitative interviews. They will then ask a member of the study team at UoY to contact the consented individuals to arrange the interview. All interviews will be conducted by an appropriately trained member of the study team at UoY.

There may be instances where a carer does not complete and return a written consent form. In this case, verbal consent for participation in an interview will be taken (and recorded) before the

interview commences (this will involve confirming that the informal caregiver has received the study information and has had the opportunity to ask questions, that they agree to the consent statements and that they agree to participate in the study). Basic demographic information (e.g. age, gender and ethnicity) will also be obtained for participating informal caregivers, at the time of the interview.

Interviews with patient participants and informal caregivers will be conducted over the telephone or via a virtual platform (where feasible, and according to patient/caregiver preference) and last up to approximately 45 to 60 minutes. Where patient participants or informal caregivers are unable/unwilling to conduct the interview via telephone/video call, efforts will be made to offer a face-to-face interview. Patient participants and their informal caregivers will be interviewed alone to enable separate accounts to be generated. Where patient participants and informal caregivers express a wish to be interviewed together, this will be conducted in a dyadic fashion. Patient participant and caregiver interviews will be conducted following the six-month post-randomisation time point.

A purposive sample of DIAMONDS Coaches will also be recruited to take part in the process evaluation. The sampling framework will include: NHS Trust and organisation; existing health and social care job role; years of service; previous experience of working with people with SMI. These details will be obtained from Coaches at the intervention training workshops. Up to four online focus groups will be held with approximately 20 Coaches. Each group will include four to six Coaches ideally from different sites. If Coaches are unable to join a group or would prefer to give their views individually, they will also be given the option of a one-to-one telephone interview.

The importance and relevance of the process evaluation will be explained to Coaches as part of the Coach training and they will be made aware that they may be contacted and asked to take part in a focus group or interview. Upon completion of their batch of intervention sessions, coaches will be asked, (via email or telephone using details shared with the study team when they joined the study), if they would like to take part in a focus group. Those who agree will be sent a PIS and consent form as well as a self-addressed return envelope. This process will be managed by the recruiting Trusts. The PIS for Coach interviews will clearly state that the interview forms part of a research exercise and is in no way a measure of Coach performance or linked to any kind of assessment of performance in their clinical role.

Coach focus groups will last approximately 45-60 minutes and will be conducted via an online platform. The interviews will be conducted by telephone and will last around 30-45 minutes.

Interview topic guides will vary by participant group and will be amended iteratively as interviews and analyses progress. Final numbers of participants will be determined by achievement of data saturation in each dataset.[66]

Qualitative analysis

All interviews/focus groups will be digitally recorded (with participant consent), anonymised and transcribed, with the transcripts forming the data for analysis. An initial thematic analysis[67] will be conducted using a framework approach.[68] An initial coding framework will be developed and transcripts checked against the framework to ensure there are no significant omissions. Codes will be examined across individual transcripts as well as across the entire data set and allocated to the framework. Using aspects of the constant comparison method of analysis, broader categories using linking codes will be developed across the transcripts.

Further analysis will be guided by the MoA framework that extends the TDF.[40] The TDF offers a robust theoretical basis for understanding implementation problems,[69] and has previously been used to frame the focus of a process evaluation of a behaviour change intervention.[70]

Integrated analysis

A triangulation protocol will be used to explore opportunities to further integrate the quantitative and qualitative data. The sources of data will include: IF assessments about adherence and quality of intervention delivery; patient participant and informal caregiver interview data about experiences of intervention receipt; and Coach interviews/focus group data about experiences about intervention delivery. Key findings will be compared (in pairs) across the datasets using a convergence coding matrix.[71] For each qualitative theme, we will investigate whether we can identify analogues in the quantitative data. We will then categorise the relationship between findings from the qualitative and quantitative data according to four categories: agreement (convergence in the data), partial agreement (complementary findings but limited overlap), silence (no overlap between quantitative and qualitative data), and dissonance (disagreement between data sets).

Economic evaluation

The health economic analysis will take the form of a within-trial cost-utility analysis (CUA) using a NHS and personal social services (PSS) perspective as recommended by NICE guidance[72] undertaken at 12-month follow-up.

Intervention costs will be collected throughout the trial to enable a bottom-up costing. We will record all costs incurred in the DIAMONDS Coach training stage and the intervention delivery stage. Training related activities, personnel, materials will be recorded as the training proceeds. The intervention session costs will be estimated based on the records of attendance of each participant. For the optional element that is the Change One Thing app, we will include the operational costs but not the development costs.

Quantities of wider health care use will be recorded by self-report questionnaires, as refined following the findings of the feasibility study. Unit costs will be taken from Unit Costs of Health & Social Care[73] and NHS National Cost Collection (NCC)[74] of the appropriate version at the time of the analysis. Other publicly available secondary sources for unit costs such as government financial reports, databases, and published literature will also be used if necessary. Unit costs will be applied to the quantities of care used to derive a patient cost profile for each patient in the trial.

Mean costs per patient will be presented for each trial arm for intervention costs and also for wider health care use, broken down into individual care categories, with mean number of contacts and costs presented individually. Standard deviations are also presented alongside means.

We will present costs based on the estimated number of patients in the total population who could receive and benefit from this intervention (i.e. beyond the trial), to provide a realistic per-patient estimate. We will estimate costs required to update and maintain the intervention to represent a realistic 'roll out' cost.

We will collect EQ-5D-5L[75] at baseline, 6- and 12-month follow-ups. The complete profile of five domains will be converted to a utility value using the appropriate method. We note that the validity

of the current EQ-5D-5L UK population tariff for the conversion has been questioned, and therefore we propose to use the methodology recommended by NICE at the time of analysis to derive utility values. These utility values will then be used to calculate Quality-Adjusted Life Year (QALY), following the area under the curve approach, [76] using the three recorded time points. The QALY will be the primary outcome of effect for the economic evaluation.

Missing data patterns will be explored by treatment arm, baseline characteristics, and values at prior time point. The results will inform the model of multiple imputation. The primary analysis of economic evaluation will be based on the imputed dataset.

Difference in costs and QALYs between treatment arms will be estimated using mixed effect regression analysis. Costs and QALYs will be the dependent variables and their respective baseline values, other baseline covariates will be used as fixed effects. The variation will be explored by adding the DIAMONDS coach variable as a random effect. Costs, comprising treatment costs and wider NHS and PSS costs, and QALY data will be combined to calculate the incremental cost-effectiveness ratio (ICER), with sensitivity analysis to account for uncertainty.

Underlying uncertainty around the decision to adopt the intervention will be assessed using non-parametric bootstrap re-sampling technique. Bootstrapping is an efficient method for calculating the confidence limits for the ICER as its validity does not depend on any specific form of underlying distribution. We will perform the bootstrap 5,000 replications and construct the 95% confidence intervals for the ICERs based on the bootstrapping results. Cost-effectiveness acceptability curves (CEACs)[77] will be constructed based on the bootstrap iterations to estimate the probability that the intervention is cost-effective at different threshold values for one QALY.

The ICER, calculated in terms of the cost per QALY, will be compared to accepted threshold values to assess the value of money afforded by the intervention over and above the control and draw conclusions with respect to the potential cost-effectiveness of the intervention.

To assess the impact of imputing missing data, we will also conduct a complete case analysis based on the participants who have both complete costs and QALYs at all timepoints, following the same analysis method as the primary analysis above. We will also conduct sensitivity analyses using pattern mixture modelling to examine the assumptions for multiple imputation methods.[78]

Workstream 5 of the DIAMONDS Programme, which does not form part of this RCT, will use health economic modelling to extend the time horizon of the trial beyond 12 months.

4. Governance and study management

The trial will be conducted to protect the human rights and dignity of the participant as reflected in the 1996 version of the Helsinki Declaration and conducted to International Council for Harmonisation/Good Clinical Practice (ICH/GCP) standards. In order to protect the trial participants the following provisions will be made/upheld; the trial has been designed to minimise pain, discomfort and fear and any foreseeable risk in relation to the treatments involved, the explicit wishes of the participant will be respected including the right to withdraw from the trial at any time, the interest of the participant will prevail over those of science and society, provision will be made

for indemnity by the investigator and sponsor and a contact name for further information will be provided.

Study participants will each be offered a £10 high street voucher as remuneration for their participation at the 6- and 12-months follow-ups and will be reimbursed any personal expenses incurred as a result of taking part (e.g. travel or childcare). Participating Trusts will be asked to handle reimbursements. They will be asked to verify any expense claims a participant might make, for example by inspecting travel receipts, and to reimburse the participant in line with local Trust policy. Trusts will then be able to invoice UoY for these amounts as part of the regular agreed invoicing process.

4.1 Study sponsorship

Bradford District Care NHS Foundation Trust will act as the lead organisation and contractual partner with the NIHR and as such will hold overall responsibility for the delivery of the programme. The University of York will act as sponsor for this RCT.

4.2 Trial management

The Chief Investigator (Prof Siddiqi) will have oversight of the entire research programme, manage the research team, and ensure timelines are adhered to. The Programme Manager (Jennifer Brown) will oversee the day to day running of the research programme. The Trial Management Group (TMG) is responsible for overseeing the day-to-day running and management of the trial. Led by the Chief investigator and the programme manager, it will include members of YTU (senior researchers, trial coordinators, trial support officer, data team and statistician), and other lead investigators. The progress of individual components of the trial will be led and overseen by co-investigators with expertise relevant to the work involved. The established Programme Management Team (PMT), composed of the Chief Investigator, co-investigators, Programme Manager, research team members, sponsor representative, and Patient & Public Involvement (PPI) representation from DIAMONDS Voice will continue to meet every other month to monitor and discuss progress.

4.3 Programme oversight

A Programme Steering Committee (PSC) was set-up at the start of the DIAMONDS programme and meets at least two times a year. Following advice from the funder – NIHR – the PSC will incorporate the functions of a trial steering committee with no requirement for a separate data monitoring and ethics committee. The PSC is convened to monitor progress throughout the duration of the research programme in relation to programme targets and milestones and will ensure the safety of study participants, by reviewing outcome and treatment data and serious adverse events. They will review serious adverse events that are judged to be related to the intervention or study participation. For the purposes of monitoring progress on the trial the PSC includes an independent statistician, a trialist, and PPI representation.

4.4 Adverse event management

Definitions

An **adverse event** is any unexpected effect or untoward clinical event affecting the participant (i.e. any unfavourable and unintended sign, symptom or disease). It can be directly related, possibly related or completely unrelated to the intervention. The severities of these events are outlined below:

A **non-serious adverse event (AE)** includes discomfort or slight worsening of symptoms. For example exacerbation of SMI that doesn't result in hospitalisation, but where care has to be escalated (e.g. referral to/ use of crisis team).

A **serious adverse event (SAE)** is an untoward occurrence (whether expected or not) that:

- Results in death
- Presents a life-threatening risk (refers to an event in which the participant was at risk of death at the time of the event)
- Requires unplanned hospitalisation, or prolongation of existing hospitalisation (i.e. A&E attendance)
    - NOTE: Hospitalisations for treatment planned prior to randomisation and hospitalisation for elective treatment of a pre-existing condition will not be considered as an SAE. Complications occurring during such hospitalisation will be AEs.
- Results in persistent or significant disability or incapacity
- Is otherwise considered medically significant by clinical members of the study team

Detecting and recording AEs and SAEs

Any adverse events (AEs) or serious adverse events (SAEs) will be reported to the Chief Investigator and will be reviewed by a clinician independent to the DIAMONDS study team. The reporting period will be from study entry up to the last follow-up visit. Details about AEs/SAEs will be captured at each clinical contact point or study assessment. AEs/SAEs that might have occurred since the previous visit or assessment are elicited from the patient by open questioning and recorded. All events related to the DIAMONDS intervention will be recorded on adverse events forms. Further information may be requested for follow up of these events. Detailed records will be kept of all adverse events.

Evaluation of AEs and SAEs

Adverse events that are deemed possibly, probably, or definitely related to participation in this study and all SAEs will be evaluated for seriousness, causality, severity and expectedness by the chief investigator and reviewed by an independent clinician/mental health specialist. All AEs/SAEs will be reviewed in terms of suspected causal relationship (e.g. unrelated, unlikely, possibly, probably, definitely) to the study intervention.

Reporting AEs and SAEs to committees

All SAEs will be reported to the sponsor and to the Research Ethics Committee (REC) in line with their guidelines. Serious events deemed unexpected and related events will usually be reported to the REC within 15 days of the event being reported. All others will be reported in the usual 6-monthly progress report. Any relevant further information will be subsequently communicated and events will be followed up until the event is resolved or a decision is made that no further follow-up is necessary. In addition, all associated investigators will be notified. The numbers and details of all AEs and SAEs will be reported to the PMT and PSC.

AEs reported by study participants that are not classified as an SAE will be reported and included in reports submitted to the PSC in agreement with the committee chair.

Where repeated adverse events (serious or non-serious) of a similar type are observed, these will be discussed with the PMT and other relevant groups and will be onward reported to the REC and Sponsor should concerns be raised in relation to the type of event and/or frequency observed.

Suicide and self-harm risk management

Inherent in the population under scrutiny is the risk of self-harm and suicide. We have developed a suicide risk protocol for the monitoring of suicide and self-harm risk during all encounters with study participants. The study team has a wealth of experience in developing and implementing risk protocols for use in trials involving psychological interventions for SMI. Where any risk to participants, due to expressed thoughts of self-harm or suicide is encountered, a risk assessment will be conducted. Prior to conducting the risk assessment, the participant will be advised that if there is a concern of risk of harm to themselves or others, that these concerns will need to be passed on to another party (for example, their GP or their care coordinator).

Level of risk will be determined through a set of six 'Exploring Risk' questions which will categorise the risk level into Level A (lowest), Level B, and Level C (highest). If a participant is assessed as having the highest level of risk, this will be reported immediately to the trust PI who will advise on trust procedures. If there is immediate risk and the PI is not available at that time, then the trust crisis team, GP out of hours, or emergency services will be called. Trusts will be advised to allocate clinical cover for the PI to ensure there is a designated contact for the protocol. All members of the study team will complete training on the risk protocol, before commencing contact with participants. Members of the study team will be provided with support following risk if required.

Duty of care

We will use YTU standard operating procedures to support researchers to report to GPs or responsible services instances where there are concerns about the health of the participant.

Researcher safety and lone working

Researcher safety is of paramount importance. We will use the YTU standard operating procedures/Department of Health Sciences policy for fieldwork and lone working (see Appendix 1). Fieldwork is defined as any research activity that involves data collection either on-site (university premises) or off-site (e.g. patient's homes, hospitals premises, and community centres). All researchers tasked with fieldwork will undertake lone worker training and conduct a risk assessment with their line manager about the specific tasks to be carried out. Researchers will be able to appoint a designated person (academic or administrative staff) who will act as a safety contact. A system will be agreed between the researcher and the designated person to communicate when the fieldwork trip has started and finished. Researchers will have regular debriefs with their line manager and the Chief Investigator to review this process and check that it is fit for purpose. Details of the lone worker policy will be included in the researcher handbook.

Statement of indemnity and complaint handling

Normal NHS indemnity procedures will apply. The University of York will also provide relevant cover. The PIS will provide participants with contact details of the Sponsor in case of complaint. If there is negligent harm during the trial, when the NHS Trust owes a duty of care to the person harmed, NHS indemnity covers NHS staff and medical academic staff with honorary contracts only when the trial has been approved by the R&D department. NHS indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm.

Monitoring quality control and assurance

Quality control will be maintained through adherence to Standard Operating Procedures (SOPs), study protocol, the principles of ICH/GCP, research governance and relevant clinical trial regulations. This trial is a low-risk study and major safety data are not anticipated. The trial will be managed in collaboration with YTU. Monitoring of study conduct and data collected will be performed by a combination of central review and site monitoring visits and/or remote monitoring to ensure the study is conducted in accordance with good clinical practice. The main areas of focus will include consent, serious adverse events, and essential study documents. All monitoring findings will be reported and followed up with the appropriate persons in a timely manner. The study may be subject to inspection and audit by Bradford District Care NHS Foundation Trust under their remit as sponsor and other regulatory bodies to ensure adherence to GCP. The investigator(s)/institutions will permit study-related monitoring, audits, REC review and regulatory inspection(s), providing direct access to source data/documents.

Data collected as part of this research includes questionnaires, clinical assessments, information from medical records, and qualitative data from interviews. Data will be collected through designed questionnaires on paper. These paper forms will be scanned at YTU and the data stored in a database where they are checked against the hard copy of the questionnaire. Data is error checked and validation checks are run against the database. Discrepancies identified during validation which require resolution are communicated to the relevant person who is in a position to obtain the information required to rectify the discrepancy. If data are found to be missing from participant completed questionnaires, participants will be contacted by one of the research team members in an attempt to collect the data.

4.5 Data management

In line with the 2018 General Data Protection Regulation and the UK Policy Framework for Health and Social Care,[79] anonymised trial data will be securely archived by the University of York for a minimum of 10 years. Personal data of participants will be stored for up to three years after the study has ended for the purpose of disseminating study findings. It is unlikely that this will take longer than 12 months; however, to ensure that participants receive adequate and full information about the study after it has finished, additional time has been allocated.

All information collected during the trial will be kept strictly confidential as detailed above. Information will be held securely in paper and/or electronic formats at the University of York. The University of York complies with all aspects of the 2018 General Data Protection Regulation and Data Protection Act 2018. Operationally this will include obtaining explicit consent from study participants to record personal details including name, postal and email address, and contact telephone numbers; and appropriate storage, restricted access and disposal arrangements for their personal details. All participants will be informed of their rights in regard to the personal information stored, including erasure, rectification and objection. All work will be conducted following the University of York's data protection guidance which is publicly available (University of York, 2018).[80]

Confidentiality

Each participant will be allocated a unique trial identification number. This number will be used to identify participants throughout the study. The master register linking participants personal and contact details with the identifier will be maintained by the York Trials Unit data manager. Only relevant members of the study team will have access to this information via a password protected

database within secure offices. A Participant Screening/Enrolment Log will be maintained, providing the dates patients were screened, whether they were eligible or not (with reason) and if consented or not (with reason). This log will not contain any identifiable patient details.

Clinical information will not be released without the written permission of the participant, except as necessary for monitoring and auditing by the Sponsor, its designee, Regulatory Authorities, or the REC. The investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

Data security

- All data will be stored in accordance with data protection requirements and will be kept either in a locked filing cabinet in a secure office or in the case of electronic data on a secure server with a password protected computer and files.
- Personal addresses, postcodes and other contact details of consenting participants will be stored on a secure password-protected server located at the University of York, for the purposes of assisting in follow-ups during the study. All personally identifiable participant data will be coded, pseudonymised by participant number in all manual and electronic files. YTU will maintain a list of participant identification numbers for all trial participants at each site.
- Interview recordings will be downloaded onto a password protected computer and deleted from the recording device. They will then be securely uploaded to a GDPR-compliant transcribing company.
- No data will be stored on a home computer or laptop.
- All data will be stored for a minimum of 10 years, which will allow time for any academic challenge to be made. All data will be deleted after this time.

Patient and Public Involvement & Engagement

The DIAMONDS Voice PPI panel (a group for people with SMI and their family members/friends who support the DIAMONDS Programme) has contributed to development of the research protocol and a small cohort of members will work with study team to ensure that: (i) the conduct of the trial minimises participant burden; (ii) approaches to recruitment are optimised, and (iii) findings are disseminated in an appropriate format. Specifically, we will seek service user input at the following stages throughout this trial:

1. Feedback on layout and size of baseline questionnaire packs (prior to participant recruitment)
2. Feedback on topic guides for interviews as part of process evaluation
3. Contribution to intervention refinement prior to the start of the main trial
4. Feedback on draft manuscripts for publication, especially lay summaries

Two co-investigators on the DIAMONDS Programme Management Group bring personal experience as a person with SMI or family member/ friend and will contribute directly to project management, and interpretation and dissemination of findings. One member of the PSC, which provides an overall steer for the project, also brings personal experience as a person with SMI.

The Diamonds Voice PPI panel meets 3-4 times per year to provide input on the study, as their perspective of how care is provided and received is invaluable for informing our understanding of factors that contribute to self-management to develop acceptable interventions as well as appropriate methods of evaluation. DIAMONDS Voice members have received research methods training and will continue to recruit to the panel when needed, and training will be updated when required. All payments made to people with SMI and family members / friends are based on NIHR INVOLVE guidance. [81]

We also have a stakeholder network of organisations with an interest in DIAMONDS, which includes clinicians working in and outside the NHS, NHS service managers and commissioners, and charitable and commercial organisations involved in physical and mental health. Members receive regular updates about the study in our newsletter.

Definition of end of study

End of study will be defined as the date at which the last participant has completed their final study process, defined as:

- Completion of final planned follow up assessment in the study, including possible qualitative interviews for the process evaluation
- Full withdrawal from follow up due to any reason

Ethical review

This protocol and the associated informed consent documents will be submitted to the required regulatory authorities (e.g. NHS Research Ethics Committee [REC] and Health Research Authority [HRA] for review and approval.

Potential risks and benefits

Individual participants may not benefit directly from this research. A PIS has been developed with the involvement of DIAMONDS Voice and gives a balanced account of the possible benefits and any known risks. It states explicitly that quality of care will not be compromised if the patient decides not to enter the trial or withdraw their consent.

5. Dissemination and impact

The outputs of this study (Phase 4 of the DIAMONDS programme) will be:

- Detailed knowledge of practicality and acceptability of the intervention from the perspective of service users and providers
- Effectiveness of the intervention that could underpin evidence-based treatment recommendations, resource allocation, and service specification for diabetes self-management in severe mental illness
- An economic model that can predict long-term outcomes and costs for interventions targeting people with severe mental illness and diabetes, which can also be adapted for other long-term conditions such as COPD

The protocol will be published in a peer reviewed journal. We aim to publish the findings of the main study in peer reviewed, academic and professional journals to ensure that clinicians and academics have prompt access to our findings.

We will produce a short newsletter summary of the results that can be distributed to all trial participants and other relevant stakeholders (e.g. commissioners, third sector organisations) and will use existing social media channels, websites, and knowledge exchange events to communicate our findings beyond academic audiences.

6. Glossary

AE	Adverse Event
BCT	Behaviour Change Technique
BDCFT	Bradford District Care NHS Foundation Trust
BMI	Body Mass Index
CEACs	Cost-Effectiveness Acceptability Curves
CMHT	Community Mental Health Team
CRN	Clinical Research Network
CSO	Clinical Studies Officers
CTC	Consent to Contact
CUA	Cost-utility analysis
GCP	Good Clinical Practice
GP	General Practitioner
HbA1c	Glycated haemoglobin
HRA	Health Research Authority
ICH	International Council for Harmonisation
IMD	Index of Multiple Deprivation
IRAS	Integrated Research Application System
LDC	Leicester Diabetes Centre
LTC	Long-term Condition
LYPFT	Leeds and York Partnership NHS Foundation Trust
MoA	Mechanism of Action
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PIS	Participant Information Sheet
PMT	Programme Management Team
PPI	Patient & Public Involvement
PSC	Programme Steering Committee
QALY	Quality Adjusted Life Year
QOF	Quality and Outcomes Framework
REC	Research Ethics Committee
R&D	Research & Development
SAE	Serious Adverse Event
SMI	Severe Mental Illness
SOP	Standard Operating Procedure
SWYPFT	South West Yorkshire Partnership NHS Foundation Trust
TEWV	Tees, Esk, and Weir Valleys NHS Foundation Trust
UKAS	United Kingdom Accreditation Service
YTU	York Trials Unit

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Appendix 1

Standard Operating Procedure for lone working and researcher safety

Section A PURPOSE

1.1 This Standard Operating Procedure (SOP) describes procedures to ensure researcher safety when working alone with trial participants.

Section B APPLICABILITY

1.1 This SOP is applicable to all trials where York Trials Unit (YTU) is responsible for, or involved in, data collection through face to face contact with trial participants.

1.2 Where a trial is not coordinated by YTU, this policy should still be followed to ensure the safety of YTU research staff.

Section C RESPONSIBLE PERSONNEL

1.1 Any YTU staff member who is required to conduct face-to-face visits with participants for reasons related to a trial (e.g. data collection, interviews).

Section D PROCEDURE FOR LONE WORKING

1.1 **Before the visit**

- Researchers should ensure that they have arranged a designated 'buddy' who will be available by telephone throughout the visit.
- The researcher should ensure that the 'buddy' is provided with the time of visit, expected duration, participant trial ID and with necessary contact numbers should they need to reach the participant (***F22: Lone worker contacts form***). This form should be held in a secure location.
- Since unforeseen circumstances (e.g. illness) could result in the designated 'buddy' not being contactable or available, a 'reserve' buddy should be identified prior to the visit and they should also be provided with the completed ***F22: Lone worker contacts form.*** This form should be held in a secure location. A copy should also be left with a member of the study research team at the researcher's office base.
- On the day of the visit the researcher should check to ensure that the 'buddy' is still available to cover the visit. If not, the 'reserve' buddy should be contacted and cover assured.

- If the visit is to be made outside normal working hours, arrangements should be made to ensure that the 'buddy' has access to the visit and contact details.

- Prior to starting the visit, the researcher should make contact with the 'buddy' by telephone or text to inform them that they are at the location and are commencing the visit.
- The 'buddy' should acknowledge receipt of this message and only then should the researcher commence the visit.

During the visit

- The researcher will carry a personal alarm throughout the fieldwork trip/ interview situation in case of emergency.
- On arrival to the interview location, the researcher will text or call the contact person.
- If the visit duration is longer than expected, the researcher should contact the 'buddy' by telephone or text message, to indicate that they have been delayed. A time of next contact should be provided.
- The 'buddy' should acknowledge receipt of this message.

- In the eventuality that a researcher is held by a participant against their will, the researcher should, if possible, contact the 'buddy' by telephone. They should ask the 'buddy' to "cancel my supervision with John" or similar. This emergency 'code' phrase should be recorded on ***F22: Lone worker contacts form***
- The 'buddy' should then contact the local police informing them that a member of staff is held against their will. The 'buddy' should provide the participant's address details.

After the visit

- The researcher should contact the 'buddy' to inform them that the visit has finished and that they are on their way back to local base.
- If the 'buddy' fails to respond the researcher should leave a message and continue to try to contact the 'buddy' using all available contact telephone numbers. An attempt should also be made to contact the reserve buddy.

- If the researcher has not been in contact with the 'buddy' 30 minutes after the visit end time, the 'buddy' should try to contact the researcher on their mobile telephone.

- If the researcher fails to respond the 'buddy' should try any other contact telephone numbers held for the researcher.
- If there is still no response, the 'buddy' should access the participant's contact details, via the trial database or the completed form. The 'buddy' should then try to contact the participant by telephone.
- If there is still no response, the 'buddy' should then try to contact the local trial coordinator, trial manager, trial administrator, research supervisor or line manager to check if they have had any contact with the researcher.
- If there is still no response, the 'buddy' should then try to contact the researcher's next of kin or emergency contact to check if they have been in contact with the researcher.
- If there is still no response, the 'buddy' should contact the local police service, informing them of the situation and providing them with the address of the participant.
- If the visit has been conducted successfully and the researcher is confirmed as 'safe', the completed ***F22: Lone worker contacts form*** should be securely destroyed (shredded).

2.0 Lone worker apps for mobile phones

A number of 'lone worker' apps are now available for most mobile phones. Should a member of staff wish to use such an app, they may do so but **only in conjunction with the above procedures** and they must also still complete the ***F22: Lone worker contacts form.***

3.0 **Additional information** **Appendix 1** contains the additional advice given in the Department of Health Sciences guidelines for students and staff undertaking interviews or other research in participant's home. This advice should be followed in conjunction with this SOP.

The current version of this guideline can be found at:

http://www.york.ac.uk/media/healthsciences/documents/rgc/DoHSGuidelinesforloneresearchupdatedMarch2016.pdf

Researchers should check this link to ensure that the advice given in Appendix A is the most recent.

Section E REFERENCES

No references were used in the writing of this SOP

Section F APPENDICES

Appendix A

PREPARATION FOR THE VISIT

- Gather all available information about the participant/family.
- If colleagues have met with the participant, check with them about the safety of a home visit.
- Make an appointment with the participant, and inform them of the visit
- Where possible have a mobile phone that is used solely for the research project, and only give participants this number or a University number. Never give your personal phone number.

VENUE

- Check the address.
- Consider the geographic area and know as much about is as you can. If the location is considered high-risk for violence or substance abuse, consider taking a colleague with you, or have a driver (colleague / taxi) wait outside during the visit.
- Check ahead whether there are any dogs in the house and whether these will be tethered or not during the visit; if concerned about an animal you should not enter/withdraw.
- Know exactly where you're going. Check weather conditions and be prepared appropriately.
- If driving be familiar with route (see below).
- Look as confident as you can and try to blend in as much as you can. Try not to look as if you are not sure of where you are going.
- Remember localities can be very different places at night than they are during the day.

BEFORE SETTING OFF

- Check equipment.
- Dress appropriately in a way that does not make you stand out. Try avoiding being too obvious about carrying equipment, such as lap top computers.

- Remember to leave your itinerary and notify colleagues of any changes. Set up a Buddy system to ensure that someone (line manager, co-worker, group secretary) has responsibility for ensuring that you have completed the home visit safely. For students, the supervisor must monitor the visits. The Buddy or supervisor should know where you are going, the time your visit starts and the expected time that it will finish.
- They should have your contact details (including next of kin) and always know where you are. Arrange to let them know when the interview has finished and that you are safe.
- The Buddy must know and agree to take on this role, and contingency plans must be in place to cover absence of the Buddy (see above)
- Agree action with the Buddy to be taken if you have not phoned in by an agreed time and do not answer a call to your mobile phone. This will include a set of escalation procedures to alert more senior management (if applicable) and the police. This is essential and must be done.
- Consider whether a code word system would be useful. This means that you can alert your Buddy / colleagues via a text or brief call that you need to be phoned so that you have an excuse to leave, or that you are in an emergency situation.
- Have some change and/or a phone card available in case you need to use a public phone. It is not always possible to get a mobile telephone signal.
- If possible, access training in recognising aggression and using de-escalation techniques.

THE VISIT

- When on public transport or walking from your car, carry your keys and mobile phone in your pocket, so that if your bag is snatched you can still drive home / get into your house. (Keys can also be used in defence if necessary).
- Remember you have a choice. If in doubt don't go in. Exercise extreme caution if you think that substance misuse may be occurring at the time of the visit, or if anyone in the household is obviously under the influence of alcohol/drugs.
- Do not show interest in people's property or whatever else is inside the house / surrounding area.
- Be aware of any delicate issues involved with discussions or interviews.
- Follow the participant in, noting locks and access and try to dissuade participants from locking you in.

- Note the layout of the house, in particular the way out and always try to sit between the participant and the exit. When offered a seat try to sit in a position that gives you access to the door.
- Before asking questions, explain why you need to know certain things and ensure people know who you are and what you are doing.
- Remember your own behaviour can trigger or prevent aggression, treat participants courteously and allow them to retain optimum control and dignity; you are a guest in their home.
- Be prepared to show some form of identity if asked.
- Consider issues of Child Protection and vulnerable adults.
- Do not underestimate the importance of body language. Avoid an aggressive stance. Crossed arms, hands on hips or raised hands will challenge and confront. Keep your distance.
- Bring the interview to a halt if the situation changes at any time. Do any of the family members give cause for concern?
- Remember the dynamics of the visit can change; such as if someone else comes into the house or room.
- If violence is threatened, leave immediately.

TRAVELLING BY CAR

- Make sure the vehicle is in good working order before setting off (and that it is insured for business use).
- Plan your journey in advance and tell someone which route you mean to take.
- If possible, and if travelling to areas that you do not know, consider using a satellite navigation aid (although this must be packed out of sight when parking).
- Do not leave valuables visible in the car, even when you are in it, and keep bags out of reach of open windows.
- When parking in daylight, consider what the area will be like after dark. If there is a chance that it will be dark when you return to your car, park near a street light if possible.
- When returning to the vehicle, quickly look around it to make sure there is no-one waiting for you.
- If you are forced to stop by another car, stay in the car, lock the doors and speak through a slightly open window.
- Make sure you know what to do if the car breaks down (i.e. who to phone, where to phone and so on).

TRAVELLING BY PUBLIC TRANSPORT

- Before setting off, have a timetable of the route using online resources such as the https://www.gov.uk/search?q=planning+your+route which allows you to plan routes using public transport. A copy of this should be given to your Buddy and if you need to vary your route, inform them.
- If possible, wait for your transport at a busy, well-lit stop or station. If this isn't possible, be vigilant at all times.
- On buses, sit downstairs near the bus driver, in an aisle seat if possible. On trains sit near the emergency alarm and familiarise yourself with the emergency procedures.
- Avoid upper decks on buses, or empty compartments on trains and also avoid these if there is only one other passenger.
- If threatened by another passenger, alert the guard/driver as soon as possible.
- Always carry the numbers of local taxi companies, as a backup.

HIGH RISE FLATS

- Always use the door entry system so that the participant knows you are on your way up.
- Be confident and know what floor you want before you get in the lift.
- Do not get into a lift if you feel unsure about its condition, e.g. doors not closing properly or the lift or lights aren't working correctly.
- Trust your instincts; do not get into a lift with a person you feel unsure about.
- If someone gets into a lift and you do not feel safe get out even if it's the wrong floor.

EQUIPMENT

- Be prepared to give up equipment/bags without a fight, things can be replaced, you can't.
- Keep a list of emergency contact numbers, including those for out of hours.
- Make sure your mobile phone is charged and that you know how to use it. Mobile phones should also be programmed for the local police number and your base number.
- Remember the limitations of mobile phones; they are unlikely to work properly in basements, lifts and high rise buildings.
- Always carry a personal alarm (available for the Department, free of charge.), check the battery and remember it is useless in the bottom of your bag.

MANAGING AGGRESSION

- Talk yourself out of problems; placate rather than provoke. Do not turn your back on someone who is behaving aggressively. Stay calm, speak gently and slowly. Do not be enticed into an argument. Never try to touch someone who is angry – this will not calm the situation.
- Recognise the limits of your own ability to deal with a situation and the time when it becomes prudent to leave; trust your instincts.
- Keep your eye on potential escape routes.
- Try to get away as quickly as possible. Move towards a place where there will be other people. Be prepared to use your personal alarm. Set it off as close to the aggressor's ear as possible and then throw it out of reach. Shout and scream – shout something practical like 'call the Police!' or 'Fire!'

ACTION FOLLOWING AN INCIDENT

- Allow yourself time to recover; seek practical support from your colleagues and manager.
- Contact the police, if appropriate.
- Seek proper medical attention for any physical injuries.
- Contact your manager.
- Report all incidents through the formal reporting procedures, including informing the Head of Department and Director of Research. This must be done.
- Share information with others who work in the area or who are likely to visit that particular address.
- Even after very minor incidents, feelings may be difficult to control and may affect your ability to deal with any further problems that arise. This is a perfectly natural reaction; if in doubt, take time out.
- Ask for a de-briefing and further counselling if necessary.
- Try to identify where control was lost and how, so that practice and training can be improved accordingly. For more comprehensive guidance on these points see the HSE http://www.hse.gov.uk/pubns/indg73.pdf