Trial/Study Protocol

Understanding barriers to increasing physical activity in chronic pain: an exploratory study to develop the SUstainable Self Effective Exercise Development (SUSSED) intervention

Trial/Study Acronym	SUSSED
Sponsor	University of Dundee
Sponsor Ref Number	2-047-19
Funder	Chief Scientist Office
Chief Investigator	Professor Lesley Colvin
REC Number	19/LO/2012
Clinical Trials Unit	Tayside Clinical Trials Unit
Clinicaltrials.gov Number	
Version Number and Date	V3 31-08-2020

PROTOCOL APPROVAL

Understanding barriers to increasing physical activity in chronic pain: an exploratory study to develop the SUstainable Self Effective Exercise Development (SUSSED) intervention.

Signatures

The undersigned confirm that the following protocol has been agreed and approved by the Sponsor and that the Chief Investigator agrees to conduct the trial/study/study in compliance with this approved protocol and will adhere to the principles of GCP, the Sponsor SOPs, and any other applicable regulatory requirements as may be amended from time to time.

Professor Lesley Colvin		5th Dec 2019
Chief Investigator	Signature	Date

LIST OF ABBREVIATIONS

AE	Adverse Event
AHP	Allied Health Professional
CI	Chief Investigator
CNORIS	Clinical Negligence and Other Risks Indemnity Scheme
CRF	Case Report Form
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
GP	General Practitioner
ICF	Informed Consent Form
IF	Incidental Findings
ISF	Investigator Site File
PA	Physical Activity
PI	Principal Investigator
PPI	Patient public involvement
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedures
S/TMF/SMF	Trial Master File/Study Master File
T/SMG	Trial Management Group
TPS	Tayside Pain Service
TSC	Trial Steering Committee

SUMMARY/SYNOPSIS

Study Title	Understanding barriers to increasing physical activity in chronic pain: an exploratory study to develop the SUstainable Self Effective Exercise Development (SUSSED) intervention.	
Study Design	Mixed methods observational study	
Study Population	Population 1: People with chronic (more than 6 months) pain referred to the NHS Tayside Pain Service. Population 2: Key Stakeholders including healthcare professionals (e.g. General practitioners (GPs)/ Allied Health Professionals (AHP)s, Nurses, pharmacists); community organisations through the Green Health Partnership, Leisure Centre Staff	
Sample Size	Population 1 (people with chronic pain): up to 45 Population 2 (stakeholders who might use SUSSED in patient care): Up to 16	
Planned study Period	1 year	
Clinical phase duration	Approximately 1 week	
Follow up phase duration	None	
Research Question 1	Objectives Using a systematic approach, to understand barriers and facilitators to PA in patients with moderate-severe chronic pain	Outcome Measures Qualitative analyses of semi-structured interviews with patients with moderate-severe chronic pain.
Research Question 2	Using subjective and objective measures, to assess PA capacity and behaviour, and the acceptability of these measures for future studies	Qualitative analyses of semi-structured interviews with patients with moderate-severe chronic pain. Quantitative analyses of questionnaires Quantitative analysis of data obtained from validated Patient reported outcome measures of activity, personal fitness trackers and activPAL monitors
Research Question 3	Using a systematic approach, to understand perceived barriers and facilitators in healthcare professionals and other stakeholders	Qualitative analyses of semi-structured interviews with healthcare professionals and other stakeholders to include the Green Health Partnership, and Leisure Centre Staff

Research Question 4	To draw together the above outcome measures, our previous work, and best available published evidence to develop the SUSSED framework for future testing.	Development of the pilot SUSSED framework.
Inclusion Criteria (Population 1)	Referred to Tayside pain service In pain for at least 6 months Pain severity: moderate to severe as assessed by pain clinic questionnaires (NRS>3) No clinical contraindications to wearing Fitbit Consented to being contacted for research Over 18	
Exclusion Criteria (Population 1)	Receiving active treatment for cancer Unable to provide informed consent	
Inclusion Criteria (Population 2)	Over 18 Member of stakeholder population, including healthcare professionals (e.g. General practitioners (GPs)/ Allied Health Professionals (AHP)s, Nurses, pharmacists); carers, 3rd sector organisations, leisure centre staff and others identified through the Green Health Partnership	
Exclusion Criteria (Population 2)	Unable to provide informed consent	

1 INTRODUCTION

Chronic pain, affecting around 20% of adults (~45% of older adults), is the leading cause of disability globally and in Scotland (1). In the UK, with an aging demographic, societal burden of chronic pain is increasing, with a need to optimise management of this chronic condition. In parallel, there has been a marked increase in opioid prescribing, despite limited evidence base for long-term efficacy, and increasing concerns about harms: effective non-pharmacological strategies are urgently needed(2, 3).

There is good evidence, with recommendations from national and international guidelines, that physical activity (PA: bodily movement resulting in energy expenditure, in any context of daily life) is one of the few safe and effective interventions for chronic pain (4, 5). Our Cochrane review found that whilst PA is beneficial for chronic pain, there is insufficient evidence to recommend any particular PA type. Current evidence is low quality, often not including participants with moderate-severe pain or adequately measuring PA adherence (6-8). Exercise levels in those with chronic pain are poor: most (>90%) are very inactive. Patient beliefs are a strong factor in determining activity levels, with a need for clear, individualised advice and support (9). To date, there has been no systematic approach to identify how to best support individuals to increase PA, by addressing all relevant factors within a personalised plan, and using proven behaviour change techniques (6-8) (5).

It seems, therefore, that most people with chronic pain are not participating in one of the few known effective strategies to improve their health and functioning: PA should be an integral part of standard care.

We need to know how to best support these individuals to adopt and sustain regular PA. Understanding factors affecting engagement in regular PA is important. Barriers and facilitators are multifactorial, with physical, psychological, social and environmental factors playing varying roles. Barriers to PA may include pain itself, or fear of increased pain. Factors relating to the individual and the type of PA may influence engagement and adherence.

Gender, ethnicity, personal control, and peer and professional support may also impact on activity engagement and adherence (10). Additional, new barriers and influencing factors arising from factors associated with the COVID-19 pandemic may now also be important and lasting.

2 BACKGROUND & RATIONALE

Theory- and evidence-based approaches are recommended to inform development of complex interventions (11, 12). Many studies only address individual motivators and capabilities, without considering wider social and environmental factors(13). Overcoming barriers should include personalised approaches to changing behaviour, while understanding individuals' needs and concerns (6, 7). The Behaviour Change Wheel (BCW, see Figure 1 (14)), mapping to Behaviour Change Technique Taxonomy (BCT) (15) provides a validated theory-based approach to designing health behaviour change interventions ready for implementation.

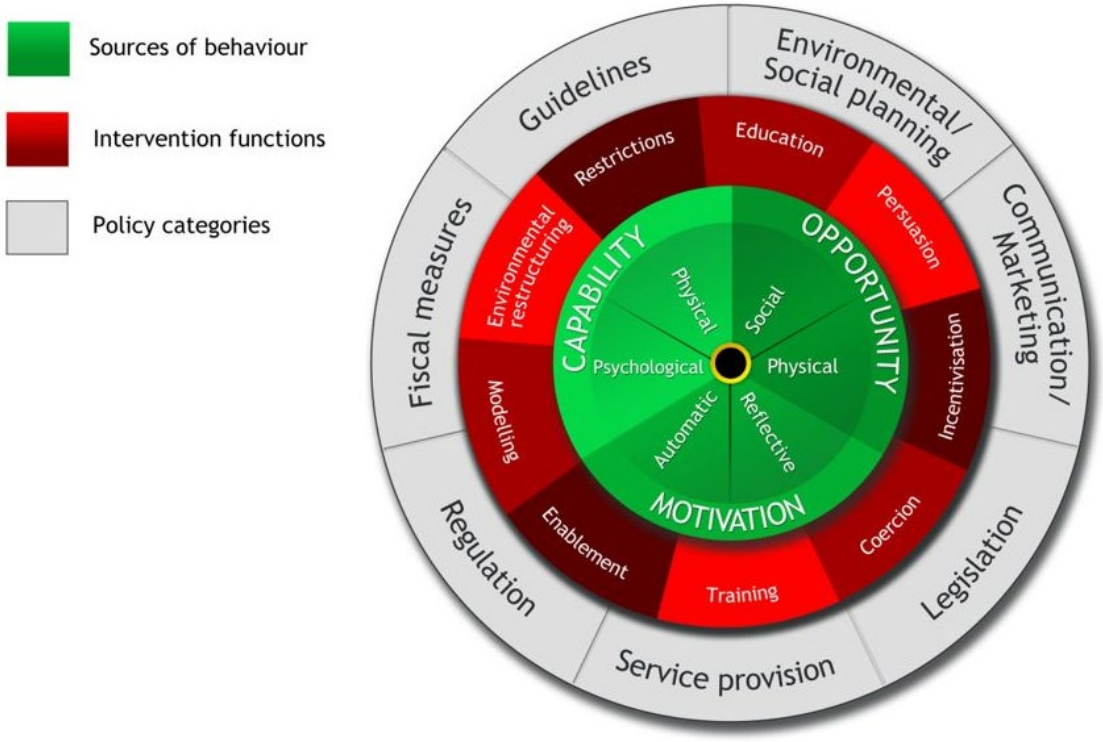

Figure 1: The Behaviour Change Wheel (BCW) (14)

At the centre of the BCW is a system of factors directly influencing behaviour (the COM-B system: Capability (physical, psychological), Opportunity (social, physical) and Motivation (automatic, reflective)), encircled by interventional (education, persuasion, training, etc.); and policy (guidelines, legislation, social planning, etc.) factors that can promote or hinder (Figure 1). The relative importance of each factor will differ between individuals. This approach has not been applied in any previous chronic pain trials, or activity-based interventions. This study is not intended to evaluate any specific behaviour change technique, but to develop a Framework for applying the right technique to the right person. If possible, the SUSSED Framework will map to proven behaviour change techniques, but this will not be possible for all techniques (e.g. improving access to public transport).

3 TRIAL/STUDY OBJECTIVES & OUTCOMES

Table 1: Research questions and Outcome Measures

Research Question	Outcome Measure:	Timepoint of outcome measured
Research question 1: Using a systematic approach, to understand barriers and facilitators to PA in patients with moderate-severe chronic pain	• Qualitative analyses of semi-structured interviews with patients with moderate-severe chronic pain.	• Study appointment 1
Research Question 2: Using subjective and objective measures, to assess PA capacity and behaviour, and the acceptability of these measures for future studies	• Qualitative analyses of semi-structured interviews with patients with moderate-severe chronic pain. • Quantitative analyses of questionnaires • Quantitative analysis of data obtained from personal fitness trackers may include; step count, distance covered, flights of steps climbed, length of sleep, calories burned. • Analysis of questionnaire of acceptability of wearing activity trackers	• Study appointment 1 • Study appointment 1 and Study appointment 2 (about one week apart) • Between Study appointment 1 and 2 (about one week) • Study appointment 2
Research question 3: Using a systematic approach, to understand perceived barriers and facilitators in healthcare professionals and other stakeholders	• Qualitative analyses of semi-structured interviews with healthcare professionals and other stakeholders.	• Single interview per stakeholder at one timepoint during study
Research question 4: To draw together the above outcome measures, our previous work, and best available published evidence to develop the SUSSED framework for future testing.	• Development of the SUSSED framework.	• Development to occur following data collection, analysis and synthesis of evidence

4 TRIAL/STUDY DESIGN

4.1 INTERVENTION

This is a non-interventional study.

4.2 TRIAL/STUDY DESCRIPTION

This study will enable the development of the SUSSED framework, using a mixed methods approach.

Up to 45 people referred to the Tayside pain service will be invited to take part in the study, aiming for a total of 40 completing the first study appointment.

They will take part in a semi-structured interview designed to assess their perceptions of the barriers and facilitators to their participation in PA.

In addition, participants will be asked to complete a questionnaire, which includes 7 validated self-report questionnaires to collect information about their pain severity, and its impact, as well as attitudes to physical activity. Demographic and basic clinical information including age, gender, height and weight will be collected together with underlying diagnosis, other co-morbidities, and postcode to enable Scottish index of multiple deprivation to be recorded.

Participants will then be provided with an activPAL4™ activity monitor (http://www.palt.com/pals/) and asked to wear this for 1 week. 20 participants who consent to wearing a Fitbit monitor will be asked to wear a Fitbit Charge 3 (https://www.fitbit.com/uk/charge3) monitor in addition to the activPAL monitor. Both the activPAL and FitBit trackers are CE marked.

Participants will be contacted after 1 week and will then be asked to complete the questionnaire as before. We will also use a number of brief questions around acceptability and feasibility of monitor use, based on our previous work (to include questions such as“did you have any problems while wearing the monitor ?”; “did you remove the monitor for any reason?“;“were there any times when you forgot to wear the monitor?” and “were there any times when you decided not to wear the monitor?”; “did you have any pain or discomfort wearing the monitor?”). Their fitness trackers will be collected and data downloaded.

To assess how behaviour change components and techniques identified by analysis of the data collected from patients can be applied in practice through existing processes and infra-structure, representative stakeholders including specialist and community-based healthcare practitioners (GPs, pharmacists, physiotherapists), carers, 3rd sector organisations, leisure centre staff and others identified through the Green Health Partnership will be interviewed. The semi-structured interviews will focus on the BCW (Figure 1), and potential mapping to the BCT including the logistics, feasibility and stakeholders' opinions of any potential interventions.

Patient and stakeholders’ interviews will be recorded, transcribed and inductively analysed into themes mapped to the 22 BCW categories (Figure 1), and any other themes that arise, assessing their nature and relative importance. Objective data from questionnaires and function measurements will be processed using standard protocols and reported using descriptive statistics. ActivPAL data will be analysed using an event-based approach

(assessing continuous periods of a single activity, e.g. walking) to allow an assessment of the quantity, pattern and timing of actual physical activity (20). Derived outcome measures will include, time spent sitting, standing and walking and time spent walking at a moderate intensity. Data from FitBitTM monitors will be collected through agreed shared access to each participant's personal FitBitTM web page. Important data will be number of steps, but will also include recorded daily distance walked, flights of stairs climbed and periods of prolonged activity. This data will be used to inform application of the SUSSED Framework, particularly in relation to assessing PA and physical capability. Collecting data from several sources allows comparison and assessment of relative (concurrent) validity, to inform future trial design and outcome measurement. Although objective monitors report walking related outcomes, other outcomes include duration and pattern of sitting (activPAL), heart rate (Fitbit), and some activity types e.g. swimming (Fitbit). This study is not primarily about assessing PA levels, but about developing the intervention and identifying how to best evaluate it in future.

Comparative analysis will explore associations between qualitative data that might affect the behaviour change response to the SUSSED Framework.

In recognition of the impact of the COVID19 pandemic on, and the uncertainties surrounding healthcare delivery, we will offer the option of video or telephone assessments, to minimise risk to participants and researchers. If face to face interviews are carried out, then appropriate, recommended safety precautions will be used.

4.3 STUDY FLOWCHART

Population 1 (patients referred to Tayside Pain Service)

The study CI together with collaborator are consultants working in the NHS Tayside Pain Service (TPS). As part of standard care, individuals referred to TPS, and triaged by the clinical team are then mailed a standardized questionnaire. This has to be returned or responded to in order to get an assessment appointment with TPS. Within this questionnaire it is standard practice to ask patients if they consent to be contacted about research or audit. If patients consent the clinical care team will assess their eligibility based on their questionnaire answers and/or medical records. If they are potentially eligible for the study the team will post a SUSSED study invitation letter, PIS and consent form to them. The mailing will contain information about how the individual can contact the study team if they would like further information or to either opt in or out of the study.

After sufficient time has been given for the PIS to be delivered to, and considered by, the potential participant, a member of CI's team will contact them on the provided contact phone number to confirm eligibility and ask if they would like to take part in the study If so, informed consent will be taken and the first study visit appointment will be arranged. For more detail of the consent process see section 5.2. Depending on the circumstances at the time, this appointment will take place either in person, for example at the Clinical Research facility at Ninewells Hospital or some other location convenient for the patient such as their home, or it will take place remotely for example via videocall or telephone.

First study appointment; researcher confirms ongoing consent,. A semi-structured interview will be carried out, the participant will complete the study questionnaire and fitness tracker(s) will be fitted, with remote instruction on how to do this if it is not a face to face consultation.

Second study appointment: One week later (7-11 days). Participant completes study questionnaire and fitness tracker(s) are returned to study team (by post if the return appointment is not a face to face

Population 2 (stakeholders such as healthcare professionals, members of relevant community organisations and leisure centre staff)

Relevant stakeholders will be identified by the study team in conjunction with the Green Health Partnership via their newsletters, emailings and face to face contact as part of the routine work of the Green Health Partnership. The CI and team will also use professional contacts to engage with health professionals e.g. GPs. We will also use our PPI partners (Versus Arthritis and Pain Concern). We will also use publically available contact details (e.g. online, telephone directory, leisure centre reception desks). They will be contacted and, if interested, provided with information about the study including the stakeholder study information sheet.

After at least 24 hours the study team will contact the stakeholder to see whether they are willing to take part. The stakeholder may also contact the study team directly if they are interested in taking part. If willing, the study team will conduct a semi-structured interview with the stakeholder, designed to assess how behaviour change components and techniques identified by analysis of the data collected from participants in population 1 can be applied in practice through existing processes and infra-structure. The interview may take place in person at a mutually agreed location such as the stakeholders' place of work, following the current COVID 19 related guidelines or it may be done remotely for example via videocall or telephone.

4.4 TRIAL/STUDY MATRIX

Population 1 (patients referred to Tayside Pain Service)

	Initial telephone contact	Study Appointment 1 (Face to face or remote contact)	Study Appointment 2 (7-11 days after Study Appointment 1)* (face to face or remote contact)
Eligibility	X		
Consent	X		
Semi structured interview		X	
Questionnaires		X	X
Demographics		X	
Fitness tracker fitted		X	
Fitness tracker removed			X

*All best efforts will be made to ensure that participants have this second appointment one week after study appointment 1. However, if this appointment takes place up to 4 days beyond 1 week (e.g. to reduce burden on participant/ avoid weekends/ Public holidays for appointments) this will not constitute a breach of protocol.

Population 2 (stakeholders such as healthcare professionals, members of relevant community organisations and leisure centre staff)

	Study appointment 1 (Face to face or remote contact)
Eligibility	X
Consent	X
Semi structured interview	X

4.5 TRIAL/STUDY ASSESSMENTS

4.5.1 Semi structured interviews with population 1

Semi structured interviews will be conducted with people suffering from moderate to severe pain at study appointment 1. Due to the current social distancing restrictions on face-to-face contacts, it is likely that this appointment will be done remotely, either via videocall or telephone.

Interviews are likely to take around 1 hour and will follow a schedule based on the COM-B framework designed to assess barriers and facilitators to physical activity:

a. Capability: physical factors that potentially impact on, and are modified by ability to exercise (e.g. disability, BMI, muscle strength, gait, pain characteristics; current medication (drug burden, particularly opioids); and psychological factors (e.g. fear avoidance, treatment expectation, catastrophizing, self-efficacy, mood, education, knowledge of pain self-management, capacity to engage, ability to plan and carry out instructions).

b. Opportunity: social and physical factors (e.g. deprivation, family support/ barriers, cost and complexity of available exercise forms, culture, geography, housing, neighbourhood, access to facilities and means to exercise, transport) influencing individuals' PA access;

c. Motivation: potentially modifiable reflective (e.g. willingness to plan and evaluate increased activity, beliefs around chronic pain and activity as treatment; outcome expectancies, goals, health, family, peer support, social contact) and automatic factors (e.g. fear of movement, emotional responses, impulsiveness) supporting or preventing activity.

Interviews will be conducted with a study researcher trained in qualitative methods and will be digitally recorded. If the interview is conducted by telephone then the recording will be conducted using an encrypted dictaphone and transcribed verbatim. For interviews conducted using video call (such as Microsoft Teams), the recording will be conducted using Microsoft teams software and automatically transferred to a secure site via Microsoft Stream where it will be transcribed verbatim similar to telephone recordings. Recordings will be deleted once they have been transcribed and all transcribed pseudonomysed data will be saved in two

locations. 1) encrypted password protected university server, 2) on a password protected encrypted memory stick.

4.5.2 Questionnaires

Self reported PA levels, pain and related factors (e.g. mood, sleep, self efficacy, catastrophizing) will be measured using validated questionnaires, routinely used in clinical practice: specifically, the Brief Pain Inventory, Depression, Anxiety and Stress Scale, Pain Self-Efficacy Questionnaire (PSEQ);Pain Catastrophising Scale (PCS); Tampa Scale of Kinesiophobia and International Physical Activity Questionnaire, and the Physical Activity Stages of Change Questionnaire;. These were used in our pilot work and were straightforward to complete and acceptable to patients. The activity tracker feasibility questionnaire will also be completed at appointment 2 to capture acceptability of wearing the tracker. Questionnaires will be completed by participants in a format that best suits them (paper or over the phone). It is likely that this will be done remotely dependent on prevailing guidelines relating to COVID19 infection it may be carried out face to face following appropriate infection control measures. In this case, paper copies of the questionnaire will be included with the delivery of activity monitor/s and returned when the activity monitor/s are returned.

4.5.3 Fitness trackers

Actual PA levels will be measured continuously for one week (including overnight), using waterproofed activPAL™ activity monitors. Using our standardised protocols, activPAL has good compliance in patients with moderate-severe pain (16). ActivPAL monitors measure free-living activity, accurately differentiating between sitting, standing and stepping, and classifying PA intensity. Their use has been validated as the “gold standard” for measuring sedentary behaviour. (19). As feedback is a recognised BCT which may potentially be recommended by the SUSSED framework, twenty participants will also wear FitBit™ activity monitors which allow data to be seen by participants. FitBit™ activity monitors estimate step count, distance walked, resulting calories burned, and flights of steps climbed. FitBit™ monitors have been shown to be as effective as pedometers in providing feedback for behaviour change, but the wider selection of outputs, may allow them to be used to measure future trial outcomes. We will gain valuable information about the feasibility and acceptability of using FitBits, as well as how they compare to the activPAL monitors. This can be used to inform approaches to outcome measurement in future studies.

4.5.4 Semi structured interviews with population 2

Due to the current social distancing restrictions on face-to-face contacts, it is likely that this appointment will be done remotely, either via videocall or telephone. Representative stakeholders including specialist and community-based healthcare practitioners (GPs, pharmacists, physiotherapists), carers, 3rd sector organisations, leisure centre staff and others identified through the Green Health Partnership, the team’s professional networks and PPI partners (Versus Arthritis and Pain Concern) and also via publically available contact details (e.g. online, telephone directory, leisure centre reception desks) will be interviewed to determine how behaviour change components and techniques can be applied in practice through existing processes and infra-structure. We have a unique opportunity to collaborate with the Green Health Partnership (NHS and Scottish National Heritage) to consult with a

wide range of non-NHS stakeholders. This also gives an opportunity for future development, testing and implementation of SUSSED through social prescribing. The semi-structured interviews will focus on the BCW framework, and potential mapping to the BCT including the logistics, feasibility and stakeholders' opinions of any potential interventions.

4.6 TRIAL/STUDY SAFETY ASSESSMENTS

Participation in this study represents minimal risk to participants.

Participants will asked to wear an activPAL fitness tracker device continuously for one week. Such trackers have now been extensively used in research studies. The SUSSED team has considerable expertise in the use of activPAL monitors, including extended use in a frail older adult population. Acceptability of the tracker will be captured in a short survey which each participant will be asked to complete at the end of the week. If the tracker becomes uncomfortable during the week the participants will be asked to remove the tracker and contact the study team.

There is a very low risk that participants will develop a skin reaction to the materials used to attach the activPAL3 device to the thigh. The attachments to be used are all hypoallergenic and medical grade to minimize this possibility. The participants will be given a contact number of the research team to call if they have any concerns and will be told to remove the device if they encounter any skin irritation. Applicable staff and patients will be trained in appropriate removal of the waterproof dressing and monitor

Some participants will additionally be asked to wear commercially-available FitBit trackers in order to compare the accuracy of the data they collect with the data collected by the activPAL devices. Again, participants will be asked to remove these if they become uncomfortable and will complete an acceptability survey at the end of the week.

Prepaid packing will be provided for return of PA monitors. On return these will be quarantined for around one week to ensure that they are free of any active viral contamination. Trackers will be cleaned, data downloaded and reset for the next participant., Participants will complete questionnaires and interviews about their chronic pain, their general health and their levels of activity. It is possible that participants may become upset or distressed as a result of these discussions. The researcher will be fully trained to assess and support the participant and to observe whether participants are becoming emotional during certain questions. If this happens the researcher will be trained to apply care and effective communication skills to support participants in the moment. The researcher will be trained and supported by the clinical team which comprises experienced clinicians who can provide further advice on what participants may need.

4.7 TISSUE

Not applicable for this study

4.8 INCIDENTAL FINDINGS

Any incidental findings (IF: previously undiagnosed condition) considered to be clinically significant will be reported to the participant’s GP and/or consultant by the PI, with the consent of the participant.

4.9 STUDY POPULATION

Population 1

All people referred to the Tayside pain service who have been suffering from moderate to severe pain for at least 6 months.

Population 2

Key stakeholders including specialist and community-based healthcare practitioners (GPs, pharmacists, physiotherapists), carers, 3rd sector organisations, leisure centre staff and others identified through the Green Health Partnership will be recruited and interviewed as part of the study.

4.10 NUMBER OF PARTICIPANTS

Population 1

A maximum of 45 patients, to achieve a total to 40 patients completing the first study appointment, will be recruited over a period of 4 months.

Population 2

Up to 16 stakeholders will take part in a one-off interview.

4.11 INCLUSION CRITERIA

Population 1

- Referred to Tayside pain service
- Pain present for at least 6 months
- No clinical contraindications to wearing Fitbit
- Consented to being contacted for research
- Pain severity: moderate to severe as assessed by pain clinic questionnaires (NRS>3)
- Over 18

Population 2

- Over 18
- Member of stakeholder population, including healthcare professionals (e.g. General practitioners (GPs)/ Allied Health Professionals (AHP)s, Nurses, pharmacists); carers, 3rd sector organisations, leisure centre staff and others identified through the study team, with the Green Health Partnership and Pain Concern/ Versus Arthritis.

4.12 EXCLUSION CRITERIA

Population 1

- Being actively treated for cancer
- Unable to provide informed consent

Individuals will not be enrolled to the trial/study if they are participating in the clinical phase of an interventional study or have done so within the last 30 days. Individuals who are

participating in the follow-up phase of another interventional trial/study, or who are enrolled in an observational study, will be co-enrolled where the CIs of each study agree that it is appropriate.

Population 2

- Unable to provide informed consent

5 PARTICIPANT SELECTION AND ENROLMENT

Population 1

The study CI, Professor Lesley Colvin together with collaborator, Professor Blair Smith are consultants within the NHS Tayside Pain Service (TPS). People who are referred to the NHS Tayside Pain Service (TPS) are asked to complete and return a questionnaire, which allows appropriate clinical triaging of the referral. There is a question on this form asking if they are willing to be contacted for research or audit projects.

After TPS receive the questionnaire, the referral is triaged to the relevant clinical team member, and an appointment is sent out. If the clinical team have identified the patient as potentially suitable at the time of triage, and the patient has agreed to be contacted, the SUSSED study invitation letter together with the patient information leaflet, blank consent form, and return envelope will be mailed out.

Due to the current social distancing restrictions it is likely that study appointments, including taking informed consent, will be carried out remotely, either via videocall or by telephone call. We will favour videocall over telephone. However, we expect that some of our potential participants may not have access to the equipment required for videocalls. We do not want to disadvantage this group and to prevent them from taking part in the study since the study seeks to establish the barriers to exercise of everyone with chronic pain. We will therefore offer either videocall or telephone calls to participants, if face to face meetings are not appropriate.

Around one week after the PIS is mailed out, a member of Professor Colvin's team will contact potential participants who have registered interest in being contacted for research and have received a SUSSED study information sheet. The team member will be trained to ask patients whether they would like to take part and to discuss the study with them if they are interested. However, the researcher will ensure that patients do not feel pressurised into taking part and understand that their clinical care will be unaffected, whether they do or do not participate in the study. If the patient says they do not want to take part they will not be asked further about the study. If the patient wants to enrol in the study, the researcher will take informed consent from the participant. For further details about his process see section 5.2.

Population 2

Relevant stakeholders will be identified by the study team in conjunction with the Green Health Partnership via their newsletters, emailings and face to face contact as part of the routine work of the Green Health Partnership. The CI and team will also use professional contacts to engage with health professionals e.g. GPs. We will also use our PPI partners (Versus Arthritis and Pain Concern). We will also use publically available contact details (e.g. online, telephone directory, leisure centre reception desks).

Relevant stakeholders will be contacted and, if interested, provided with information about the study including the stakeholder study information sheet. After at least 24 hours the study team

will contact the stakeholder to see whether they are willing to take part. The stakeholder may also contact the study team directly if they are interested in taking part. If willing, the study team will conduct a semi-structured interview with the stakeholder, designed to assess how behaviour change components and techniques identified by analysis of the data collected from participants in population 1 can be applied in practice through existing processes and infra-structure. Given the current restrictions on face to face contact it is likely that these interviews will take place remotely, via telephone call or video call.

5.1 IDENTIFYING PARTICIPANTS

Population 1

All individuals over the age of 18, with capacity to participate, who opt in to attending the TPS, by completion of the clinic questionnaire, will potentially be eligible. When completed clinic questionnaires are returned to the TPS for triage, the clinical team will assess those individuals who have indicated that they are willing to be contacted for research, to see who may be suitable for the SUSSED study. They will send those individuals a SUSSED study patient information sheet together with an invitation letter and consent form. A member of Professor Colvin's team will contact individuals who have indicated their willingness to be contacted for research. They will allow around one week from the information sheet being posted out.

Population 2

We will use our links with the Green Health Partnership to identify relevant stakeholders via their newsletters, emailings and face to face contact that is part of their routine work. The CI and team will also use professional contacts to engage with health professionals e.g. GPs. We will also use our PPI partners (Versus Arthritis and Pain Concern). We will also use publically available contact details (e.g. online, telephone directory, leisure centre reception desks).

5.2 CONSENTING PARTICIPANTS

Population 1

Eligible participants will be consented by the study researcher. Due to current social distancing regulations it is likely that this process will be done over the telephone or via video call, if the researcher is happy that the participants has a full understanding of the study and is voluntarily consenting to take part. Dependent on individual circumstances and following the current rules on social distancing and reducing risk of transmitting COVID infection, it is possible that this appointment may take place at the Clinical Research Facility, or, if more convenient for the patient, at the patient's home or equivalent. If incurred, travel costs will be reimbursed. The study researcher will follow the University of Dundee safety policy arrangement for Fieldwork (https://www.dundee.ac.uk/safety/policy/general/spa48-2010/).

The researcher will read through the consent form with the participant and ask them to write their name, sign and date the form. If this is being done remotely they will ask the participant to return the completed consent form either by post in the included freepost addressed envelope or by photographing the form and emailing it to the researcher via NHS email. The researcher will explain these options to the participant and ask which option the participant prefers. The researcher will record the details of this consent conversation in a log. When the consent form is returned to the researcher, either by post or by a photograph, the researcher will countersign and date the form and return a copy to the participant.

The study team will then arrange for fitness tracker/s and questionnaires to be provided to the participant. These may be delivered by mail or in person by the study team, ensuring social

distancing appropriate to the national guidelines at the time is maintained. A second video or voice call will then be arranged to complete the first study appointment.

Where a participant requests to speak with a physician from the study team the consent process will not be completed until the participant has spoken to the physician and had all their questions answered to their satisfaction.

If a participant, who has given informed consent, loses capacity to consent during the study the participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant

Population 2

Members of the relevant stakeholder population will be consented by the study researcher prior to the semi-structured interview. It is likely that this appointment will take place remotely, via telephone voice or video call. As for Population1, participants will be asked to post or email the consent form to the researcher so that the researcher can countersign the form. Details of the consent conversation will be added to a log. A copy of the completed form will be sent to the participant.

The informed consent process will be conducted in compliance with TASC SOP07: Obtaining Informed Consent from Potential Participants in Clinical Research

5.3 SCREENING FOR ELIGIBILITY

Eligibility will be confirmed by the clinical team on return of the clinic questionnaire. This will be confirmed by the study researcher at the first contact phone call, prior to taking informed consent.

5.4 INELIGIBLE AND NON-RECRUITED PARTICIPANTS

Ineligible individuals will be thanked for their interest in the study and will take no further part.

5.5 RANDOMISATION

5.5.1 Randomisation

Not required.

5.5.2 Intervention Allocation

Not required

5.5.3 Withdrawal procedures

Participants will be informed that they are free to withdraw from the study at any time. We will request that any data collected up until the point of withdrawal be included for analysis. Participants will not be replaced.

6 DATA COLLECTION & MANAGEMENT

6.1 DATA COLLECTION

Due to current social distancing guidelines, it is likely that study appointments will be conducted remotely, for example by voice or video call. This is likely to mirror the way in

which the Tayside Pain Service operates its clinical activity. If risks of COVID infection can be minimised and depending on prevailing guidelines, appointments may be conducted face to face either in the clinical research facility (CRF) at Ninewells Hospital, Dundee or at participants' homes.

6.1.1 Qualitative analysis

Following consent, the first study appointment will be arranged. Semi structured interviews of participants will be conducted by the study researcher, who will be trained in qualitative research.. Interviews, which will last approximately one hour, will be recorded onto encrypted digital media and guided by a topic guide. Audio recordings will be transferred from the encrypted recorders onto the University of Dundee secure network using a password-protected University of Dundee computer. Following transfer, the audio file will be removed from the encrypted digital recorder. Audio files will be identified using the participant unique study ID. The key that links this study ID number to the identity of the participant will be stored securely on a University of Dundee computer for study management purposes. Audio files will then be transcribed by the study researcher. It is possible that the interviewee may compromise their identity or those of others during the interview process. In this case, the transcriber will assign non-identifiable labels (e.g. interviewee 1) to the participant.

Interviews with stakeholders will be carried out by the study researcher and these are also likely to be done remotely via voice or video call. It is possible that they may be carried out at convenient, private locations e.g. at the stakeholders' place of work, or at the CRF, Ninewells, if more convenient, dependent on the prevailing risk of COVID infection.

6.1.2 Quantitative analysis

6.1.2.1 Validated questionnaires

Validated questionnaires will be completed by participants at study appointments 1 and 2: Brief Pain Inventory, Depression, Anxiety and Stress Scale, Pain Self-Efficacy Questionnaire (PSEQ);Pain Catastrophising Scale (PCS); Tampa Scale of Kinesiophobia and International Physical Activity Questionnaire (short form, last 7 days), The Physical Activity Stages of Change Questionnaire. Participants will receive paper copies of the questionnaires in their delivery with the activity monitor/s. The participant will then have the choice to fill out the paper copy of the questionnaire or have the questions read out loud by the researcher. Participant's preference will be discussed with a member of the study team prior to the participant's first appointment. Data will then be collected either by a paper copy of the questionnaire which can be returned to the study team by provided freepost or by the interviewer reading out the questionnaire and recording the answer by completing the paper questionnaires. Questionnaire data will then be entered into an electronic data management system (Excel) held on University of Dundee server. Analysis will be carried out using SPSS or equivalent statistical software.

6.1.2.2 Fitness tracker data

Participants will be instructed on how to fit the activPAL monitor at study appointment 1 and advised to wear this continuously for seven days. At the second, remote study appointment they will be instructed how to remove the trackers and how to return them to the study team They will be given an instruction leaflet on how to fit, use and remove the activPAL trackers. Trackers will either be collected and returned to the study team by courier or collected by a member of the study team, while observing social distancing guidelines. The data from the activPAL trackers will be downloaded onto University of Dundee servers where it will be identified using a study ID number. ActivPAL data will be analysed using an event-based

approach (assessing continuous periods of a single activity, e.g. walking) to allow an assessment of the quantity, pattern and timing of actual physical activity (20). Derived outcome measures will include, time spent sitting, standing and walking and time spent walking at a moderate intensity.

20 participants will also be asked to wear a Fitbit. The study team will create individual Fitbit accounts for each of these participants. These accounts will not use the individuals' real names, and will be linked to email accounts generated by the University of Dundee IT. Participants' date of birth, gender, height and weight will be entered into the accounts. Location service will be disabled on the Fitbit account. Fitbit have agreed to a take over by Google, and terms of this agreement are likely to be settled in 2020. At the moment we cannot be sure what the implications of this agreement will be. Both companies have issued statements that they will respect existing policies on data storage and sharing. Since some people may not be in agreement with sharing their data with multinational companies such as Fitbit or Google, we will provide the option to consent to wearing the ActivPAL only. Data from FitBit monitors will be downloaded from the individual accounts opened for each participant. Important data will be the number of steps, but will also include recorded daily distance walked, flights of stairs climbed and periods of prolonged activity. These data will be extracted from the Fitbit accounts of individual accounts into Excel spreadsheets. Data will be saved in an anonymised format using study ID.

Participants will be asked to complete a short questionnaire at appointment 2 to assess acceptability of wearing the trackers. Questionnaires will be read out to the participant and their responses recorded in the paper questionnaire by the researcher.

6.2 DATA MANAGEMENT SYSTEM

Data management will be conducted in compliance with TASC SOPs on Data Management, including TASC SOP53 Data Management Systems in Clinical Research.

The data management system (DMS) will be Excel, as approved by Sponsor and with guidance from the study statistician. Data collected on the ActivPAL fitness trackers will be analysed by collaborators at Glasgow Caledonian University. Anonymised data will be shared and analysed.The DMS will be based on the protocol and CRF for the study and individual requirements of the investigators. The CRF will collect only information that is required to meet the aims of the study and to ensure the eligibility and safety of the participant. The study database will be compliant with TASC SOP53 Data Management Systems in Clinical Research.

The database is managed in line with all applicable principles of medical confidentiality and data laws. The Data Controller will be the University of Dundee and the Data Custodian will be CI.

The PI may delegate CRF completion but is responsible for completeness, plausibility and consistency of the CRF. Any queries will be resolved by the PI or delegated member of the study team.

Database lock will be conducted in compliance with TASC SOP32 Locking Clinical Study Databases.

7 STATISTICS AND DATA ANALYSIS

7.1 SAMPLE SIZE CALCULATION

No formal sample size calculation was made for this exploratory study. We are aiming for a total of 40 patients completing the first study appointment. While we do not anticipate a high dropout rate from participants who have actively expressed an interest in taking part, there may be unforeseen circumstances that prevent study appointments being conducted, even after an appointment has been agreed. The non-attendance rate at routine clinic appointments is 12-15%, so we have extrapolated this to allow for up to an additional 5 patients being approached/ appointed (ie a total of 45, or 40 patients, whichever is reached sooner).

7.2 PROPOSED ANALYSES

Specific analyses will be detailed in the study statistical analysis plan which will be finalised prior to datalock.

7.2.1 Qualitative Analysis

Recordings of the semi-structured interviews will be analysed using framework analysis.

7.2.2 Quantitative analysis

7.2.2.1 Fitness tracker

An assessment of the level of PA undertaken by each participant will be made by analysing the variables, which include:

Feasibility outcomes: Number of days worn; Reported problems with wearing the monitor; Reported pain or discomfort while wearing the monitor; Reported duration and reasons for removing the monitor early (activPAL) or not wearing the monitor (FitBit).

Primary physical activity outcomes that are comparable between monitors:

Number of steps taken; Time spent in MVPA (moderate to vigorous physical activity). [For the activPAL this will be assessed as the time spent walking at a cadence of >= 100 steps/minutes; for the FitBit this will be the sum of time spent “fairly active” and time spent “very active”]

Secondary exploratory physical activity outcomes:

For the activPAL:

Total time spent walking; Time sent standing; Number of sit to stand transitions; Time spent sitting; Time spent in prolonged (>=30minutes) sitting (waking hours)

For the FitBit: Distance walked; Number of floors climbed; Time spent sedentary; Time spent in light activity; Time in bed; Time asleep; Time awake; Number of awakenings; Time spent in in REM, light and deep sleep

Three types of analysis will be conducted:

(1) Feasibility of using the monitors will be established by descriptive information on the quantity (number of days worn) and quality (usable days of data) of data collected from each monitor. Descriptive information will be gathered on comfort of use and reasons for non-wear, from the feasibility questionnaire.

(2) The cross-sectional daily physical activity (including patterns of activity) of participants will be reported using descriptive statistics. This information will be used to characterise participants, and individual physical activity levels will be used in conjunction with interview information to develop the SUSSED framework.

(3) For people who wore both the activPAL and the Fitbit, the concurrent agreement of the primary physical outcomes outcome measures (which are assessed by both monitors) will be assessed.

7.2.2.2 Validated questionnaires

Information from the questionnaires will be used to inform the SUSSED framework. Questionnaire data will also be compared with data collected by the Fitness trackers.

7.3 MISSING DATA

Plans for handling missing data will be detailed in the statistical analysis plan.

7.4 TRANSFER OF DATA

Personal data will remain within NHS Tayside/University of Dundee.

8 STUDY MANAGEMENT AND OVERSIGHT ARRANGEMENTS

8.1 STUDY MANAGEMENT GROUP

The study will be co-ordinated by a Study Management Group (SMG), consisting of e.g. the grant holder Principal Investigator (PI), co-Investigators, TCTU trial manager, study researcher, representatives from the Green Health partnership and PPI input through Pain Concern and/or Vs Arthritis. The SMG will also oversee the conduct and progress of the study, with minutes of meetings maintained in the TMF

8.2 TRIAL STEERING COMMITTEE

No TSC will be established since its remit will be carried out as part of the SMG.

8.3 DATA MONITORING COMMITTEE

No DMC will be established since this is a non-interventional study and there are no participant safety concerns.

8.4 INSPECTION OF RECORDS

The PI, and co-Is and all institutions involved in the study will permit study related monitoring, audits, and REC review. The PI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

9 GOOD CLINICAL PRACTICE

9.1 ETHICAL CONDUCT OF THE STUDY

The study will be conducted in accordance with the principles of good clinical practice (GCP). All members of the research team will have appropriate training.

In addition to Sponsorship approval, a favorable ethical opinion will be obtained from the appropriate REC and appropriate NHS R&D approval(s) will be obtained prior to commencement of the study.

9.2 CONFIDENTIALITY AND DATA PROTECTION

The PI and study staff will comply with all applicable medical confidentiality and data protection principles and laws with regard to the collection, storage, processing and disclosure of personal data.

The PI and study staff will also adhere to the NHS Scotland Code of Practice on Protecting Participant Confidentiality or equivalent.

All study records and personal data will be managed in a manner designed to maintain participant confidentiality. All records, electronic or paper, will be kept in a secure storage area with access limited to appropriate study staff only. Computers used to collate personal data will have limited access measures via user names and passwords.

Personal data concerning health will not be released except as necessary for research purposes including monitoring and auditing by the Sponsor, its designee or regulatory authorities providing that suitable and specific measures to safeguard the rights and interests of participants are in place.

The PI and study staff will not disclose or use for any purpose other than performance of the study, any personal data, record, or other unpublished, confidential information disclosed by those individuals for the purpose of the study. Prior written agreement from the Sponsor will be required for the disclosure of any said confidential information to other parties.

Access to collated personal data relating to participants will be restricted to the PI and appropriate delegated study staff.

Where personal data requires to be transferred, an appropriate Data Transfer Agreement will be put in place.

Published results will not contain any personal data that could allow identification of individual participants.

9.3 INSURANCE AND INDEMNITY

The University of Dundee is Sponsoring the study.

Insurance – The University of Dundee will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study.

Where the study involves University of Dundee staff undertaking clinical research on NHS patients, such staff will hold honorary contracts with Tayside Health Board which means they will have cover under Tayside's membership of the CNORIS scheme.

Indemnity The Sponsor does not provide study participants with indemnity in relation to participation in the Study but have insurance for legal liability as described above.

10 ADVERSE EVENTS

10.1 DEFINITIONS

Adverse Event (AE)	Any untoward medical occurrence in a clinical research participant which does not necessarily have a causal relationship with study participation
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life threatening • requires hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability or incapacity • is a congenital anomaly or birth defect • Or is otherwise considered serious

10.2 RECORDING AND REPORTING AE

All SAEs will be recorded on the AE Log in the CRF and will be assessed for severity by the PI or delegate. SAEs will be recorded from the time a participant consents to join the study until the participant's last study appointment.

The Investigator will make a clinical judgment as to whether or not an AE is of sufficient severity to require the participant's removal from the study. A participant may also voluntarily withdraw from treatment due to what he or she perceives as an intolerable AE. If either of these occurs, the participant should, if required, be offered an end of study assessment and be given appropriate care under medical supervision until symptoms cease, or the condition becomes stable. SAEs will be followed up until 30 days after participant's last appointment.

The PI or delegate will ask about the occurrence of SAEs and hospitalisations at every appointment during the study. **SAEs which are both unexpected and related to study participation** will be submitted on an HRA NCTIMP Safety Report form to the REC by the PI, within 15 days of becoming aware of the SAE, and copied to the Sponsor Research Governance Office.

Worsening of the condition under study will not be classed as an AE, but will be defined as an outcome. Pre-specified outcome(s) will not be classed as an AE but as an outcome. Elective admissions and hospitalisations for treatment planned prior to randomisation, where appropriate, will not be considered as an AE. However SAEs occurring during such hospitalisations will be recorded.

11 ANNUAL REPORTING REQUIREMENTS

Annual reporting will be conducted in compliance with TASC SOP 15: Preparing and Submitting Progress and Safety Reports in CTIMPs and Non-CTIMPs, as a condition of sponsorship and as a condition of a favourable opinion from a REC. An HRA Annual Progress Report for NCTIMPs will be prepared and submitted by the PI to REC, and copied to the Sponsor, on the anniversary date of the REC favourable opinion.

Any safety reports additional to SAE reports, for example, reports of a DMC, will be sent by the PI to REC, with a Safety Report Form, and to the Sponsor.

12 STUDY CONDUCT RESPONSIBILITIES

12.1 PROTOCOL AMENDMENTS, DEVIATIONS AND BREACHES

Refer to TASC SOP 30: Substantial Amendments in Clinical Research

The PI will seek approval for any amendments to the Protocol or other study documents from the Sponsor, REC and NHS R&D Office(s). Amendments to the protocol or other study docs will not be implemented without these approvals.

In the event that a PI needs to deviate from the protocol, the nature of and reasons for the deviation will be recorded in the CRF, documented and submitted to the Sponsor as potential breach. If this necessitates a subsequent protocol amendment, this will be submitted to the Sponsor for approval and then to the appropriate REC and lead NHS R&D Office for review and approval.

In the event that a serious breach of GCP or protocol is suspected, this will be reported to the Sponsor Governance Office immediately

12.2 STUDY RECORD RETENTION

Archiving of study documents will be for a minimum of five years after the end of study, as per CSO conditions of award.

12.3 END OF STUDY

The end of study is defined as database lock. The Sponsor, and/ or the PI have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The PI will ensure that any appropriate follow up is arranged for all participants.

A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.

13 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

13.1 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analysed and tabulated, and a clinical study report will be prepared.

13.2 PUBLICATION

The clinical study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.

Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

13.3 PEER REVIEW

This project has been funded by the CSO following a competitive review process.

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