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Protocol for a pragmatic feasibility randomised controlled trial of peer coaching for adults with long term conditions: PEER CONNECT

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Complete List of Authors:	Dennett, Rachel; Torbay and South Devon NHS Foundation Trust; University of Plymouth Thompson, T; University of Plymouth, Peninsula Medical School Faculty of Health Clyne, Wendy; University of Plymouth Straukiene, Agne; Torbay and South Devon NHS Foundation Trust Davies-Cox, Helen; Torbay and South Devon NHS Foundation Trust Hosking, Joanne; University of Plymouth Centre for Mathematical Sciences Bones, Krystina; Torbay and South Devon NHS Foundation Trust Weight, Olivia; Torbay and South Devon NHS Foundation Trust Elston, Julian; Torbay and South Devon NHS Foundation Trust; University of Plymouth
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Title: Protocol for a pragmatic feasibility randomised controlled trial of peer coaching for adults with long term conditions: PEER CONNECT

Rachel Dennett[1,2] 0000-0003-0400-0502

Tom Thompson[2] 0000-0002-6366-9743

Wendy Clyne [2,3] 0000-0003-1523-700

Agne Straukiene [1]

Helen Davies-Cox[1]

Joanne Hosking [2]

Krystina Bones [1]

Olivia Weight [1]

Julian Elston[1, 2] 0000-0003-1378-5030

[1]Torbay and South Devon NHS Foundation Trust, Torbay, UK

[2]Faculty of Health, University of Plymouth, Plymouth, UK

[3]NIHR Research Design Service (RDS) South West, UK

Corresponding author Rachel Dennett rachel.dennett@plymouth.ac.uk

ABSTRACT

Introduction

Patients with low levels of knowledge, skills, and confidence to manage their health and wellbeing (activation) are more likely to have unmet health needs, delay seeking healthcare, and need emergency care. NHS England estimates that this may be applicable to 25-40% of patients with long-term health conditions. Volunteer peer coaching may support people to increase their level of activation. This form of intervention may be particularly effective for people with low levels of activation.

Methods and analysis

This single site, two-arm randomised controlled trial has been designed to assess the feasibility of conducting a definitive trial of volunteer peer health and wellbeing coaching for people with long-term health conditions (multiple sclerosis, rheumatoid arthritis or chronic pain) and low activation. Feasibility outcomes include recruitment and retention rates, and intervention adherence. We will measure patient activation, mental health and wellbeing as potential outcomes for a definitive trial. These outcomes will be summarised descriptively for each time point by allocated group and help to inform sample size calculation for the definitive trial. Criteria for progression to a full trial will be used.

Ethics and dissemination

Ethical approval has been granted by the London - Surrey Research Ethics Committee, reference 21/LO/0715. Results from this feasibility trial will be shared directly with participants, presented at local, regional, and national conferences and published in an open access journal.

Strengths and limitations of this trial

- It specifically targets patients with low levels of patient activation
- It utilises a novel volunteer peer coaching intervention for out-patients with long-term conditions based on an evidence-based and manualised training programme delivered online
- The research team includes academics, clinical service members and public contributors
- As a single site study the transferability of the trial's findings to other sites may be limited

INTRODUCTION

NHS England estimates that 25-40% of patients in England have low patient activation, defined as poor knowledge, skills, and confidence to manage health and wellbeing (Level 1 or 2 on the Patient Activation Measure (PAM)).[1] These patients are more likely to have unmet health needs, delay seeking healthcare, and need emergency care. Activation level is a modifiable factor, and it is likely that people with low activation have most to gain from an intervention designed to increase patient activation levels. Supporting self-management in people with a health condition is one of six key components of the Personalised Care Model (PCM) to address low activation as set out in The NHS Long Term Plan.[2] The PCM focuses on an individual's strengths and assets alongside working towards improvements in health conditions based on a 'what matters to me' approach.

One emerging approach from the literature to support self-management is health and wellbeing coaching.[3] Nationally, programmes have been developed primarily to support patients with lifestyle changes.[4] These recommend health professionals deliver coaching alongside their clinical work. However, national roll out and adoption of these programmes has been slow, which may be in part due to increasing demand on services and lack of resources due to stagnating budgets.[5] An alternative approach to staff delivery of coaching services is to involve patients with lived experience as coaches (peer coaches) especially if they are highly activated (PAM Level 3 and 4). There is growing evidence for the effectiveness of peer coaching provided via a range of delivery modes; in-person[6, 7]; telephone[8, 9] and digital.[10] Recent randomised controlled trials of peer coaching have included people with diabetes[8, 11, 12] and chronic pain.[7, 13, 14] These studies have

demonstrated improvements in perceived physical activity (PA)[8] , quality of life (QoL)[8, 12], pain[8] and depression.[11, 12] In contrast, Matthias and colleagues reported no statistically significant between-group differences at six (estimate(SE) 0.01 (0.23), CI(-0.45,0.46)) or nine-months (estimate(SE) 0.07 (0.24), CI(-0.40,0.54)) following their effectiveness trial of a peer coach-delivered pain self-management intervention versus controls who received a class on pain and pain self-management.[7] However, several trials have reported barriers to implementing this kind of intervention which guides towards methods to minimise or overcome potential barriers.

A number of studies have highlighted potential challenges of peer coaching such as coach wellbeing, [13] low intervention adherence and high drop-out rates).[7, 8, 12] A recent feasibility RCT of peer mentorship for people with osteoarthritis in the UK reports a mixed picture with challenges in matching coaches to peers and difficulties with coach retention alongside positive reports of coach enjoyment and satisfaction.[6, 15] We have not located any studies of peer coaching that have targeted peer coaching interventions at patients reporting low levels of activation. People with low levels of activation stand to benefit most from an intervention designed to improve confidence, problem solving and ability to manage their health care and wellbeing. This may in turn impact use of health and social cares resources, and could feasibly be delivered by peers (others with long term conditions) with high levels of activation to negate the issues of resource within the NHS.

This paper describes the trial protocol for the PEER CONNECT study, a two-arm randomised controlled feasibility trial of peer coaching for people receiving out-patient care for one of three long-term health conditions; multiple sclerosis, rheumatoid arthritis or chronic pain. The peer coaching service will only be offered to people with low levels of patient

activation. It provides up to 14 coaching sessions delivered over six months which decrease in frequency over time. Volunteer peer coaches (confirmed to have high levels of activation) will attend a comprehensive training programme that follows a manualised coaching approach and includes independent and group learning sessions delivered online. In addition, they will receive regular individual and group supervision. The logic model for the intervention is illustrated in Figure 1.

Figure 1 here

Objectives

Our research question is:

Is it feasible to undertake a future definitive multi-centre RCT to determine the effectiveness of a targeted peer coaching intervention on the health and wellbeing of people with long-term health conditions and low activation attending outpatient services?

Our trial feasibility objectives are:

1. Are we able to identify, recruit, retain and follow-up eligible volunteer coaches and peers?

2. What is a sustainable number of peers per volunteer coach?

3. Are trial procedures acceptable to participants (peers and volunteer coaches)?

4. To estimate parameters needed to inform future sample size calculation

5. Are trial outcome measures acceptable to participants (peers)?

6. Does the trial demonstrate evidence to suggest that the coaching holds promise as an effective intervention?

Definitions

Within this paper the following key definitions are used:

- Peers: Participants eligible to receive coaching
- Volunteer peer coaches: Participants eligible to train to deliver coaching to peers

METHODS AND ANALYSIS

Study design

This research is a single site, two-arm, pragmatic randomised controlled feasibility trial. Eligible participants will be randomised 1:1 to either the intervention arm which includes (up to) 14 sessions of peer coaching over six months and their usual care, or the control arm who receive usual care only. Embedded within this feasibility study is a qualitative component that will include individual interviews with volunteer coaches and peers, clinic and peer coaching staff, and people who decline to take part in the interventional aspect of the study. All aspects of the trial protocol have been approved by the London - Surrey Research Ethics Committee, reference 21/LO/0715.

Participants

Eligibility criteria (peers and coaches)

Eligible participants will:

- Be aged 18 years or older (peers and volunteer coaches)

- Attend a rheumatology, pain or multiple sclerosis out-patient clinic (peers and volunteer coaches)
- Score PAM Level 1 or 2 (peers), PAM 3 or 4 (volunteer coaches)
- Be willing and able to engage in the six-month intervention (peers and volunteer coaches)
- Be willing and able to commit to undertaking assessments at baseline, six and nine months (peers).
- Have capacity to provide informed consent (peers and volunteer coaches)
- Have sufficient fluency in English to be able to engage with the intervention and trial material (peers and volunteer coaches)
- Not be participating in any other observational or interventional research trial

Recruitment

This trial aims to recruit volunteer coaches and peers to take part in the intervention. Coaches, peers, clinic and service delivery staff, and people who decline to take part in the study will also be invited to take part in the qualitative component of the research.

Recruitment of volunteer coaches and peers

Potential volunteer coaches and peers will be recruited from the multiple sclerosis, rheumatology and chronic pain out-patient clinics at a single NHS Trust (Torbay and South Devon NHS Foundation Trust (TSDFT)). Figures 2 and 3 indicate the research journey of

eligible participants. Following initial telephone screening potential participants will provide consent to complete the PAM to confirm eligibility as a volunteer coach or peer.

Figures 2 and 3 here

Consent

Participants will be offered a choice of four options for providing informed consent:

1. In-person signed form with scanned copy stored electronically on a TSDFT secure drive.

2. Video-recorded using MS Teams and stored securely as above.

3. Completed via Jisc (https://www.onlinesurveys.ac.uk/) with exported record stored securely as above.

4. Postal signed consent form, scanned on receipt and stored as above.

Randomisation

Following baseline data collection, eligible peers will be randomised to either the intervention or control arm on a 1:1 ratio using random permuted blocks, stratified by out-patient clinic. The randomisation list will be generated and stored by a statistician not involved in the trial, and allocation will be accessed through a web-portal hosted by the University of Plymouth Peninsula Clinical Trials Unit.

Blinding

Blinding of participants will not be possible due to the nature of the intervention. Due to restricted capacity not all members of the research team will be blinded. The trial statistician will be blinded to allocation.

Intervention and setting

Setting

All participants will be recruited from TSDFT, a district general hospital in the South West of the United Kingdom (UK).

Control arm

Usual care is defined as access to services and treatment provided as routine care, examples of which include attending out-patient clinic appointments, referral to therapies, and signposting to community or support services as required.

Intervention arm

The intervention includes up to 14 sessions with a volunteer coach delivered over six months. Sessions are expected to last from 15-60 minutes and will be provided in a COVID-19 secure environment either on-line, by telephone or face-to-face. A flexible framework for the coaching will be used to facilitate a personalised approach with a suggested format of one session per week for the first two months, followed by fortnightly sessions for two months and monthly sessions thereafter. Peers will be supported to produce a coaching plan with associated goals at the end of each session. A brief summary of the content,

duration, and mode of coaching delivery will also be recorded. Missed planned sessions (non-attendance) will be recorded by the volunteer coach. In addition, peers will be asked to report any adverse events (AEs) they have experienced and rate their experience of being coached.

Volunteer coach training

Volunteer peer coach training will include eight structured 90-minute live sessions supported by interactive online learning tasks. Training will be delivered by the TSDFT volunteer peer health and wellbeing coaching service, the 'Health Connect Coaching Programme'. Sessions will draw on evidence-based behavioural change methods[16], motivational strategies[17], and communication techniques. The content will also draw on evidence-based materials to improve health and wellbeing such as Making Every Contact Count (MECC)[18] , Five Ways to Well Being[19] , and NHS health coaching programmes .[4] The intervention will emphasise:[20]

- A patient-centred approach where patients determine their goals
- Active learning or self-discovery
- A problem-solving focus to work towards goals
- Regular peer feedback on implementing the coaching plan

Training will initially be completed virtually using Microsoft Teams, with a view to offer face-to-face training in the future should COVID-19 restrictions allow. Each 90-minute session will include a break. There will be two training sessions each week for four consecutive weeks.

Training will total a minimum of 15 hours for each volunteer coach, including homework activities, practical sessions, and on-line modules.

The training content covers:

- Background to personalised care and why it matters
- How this volunteer role has been developed and why
- Stages of behaviour change and how this relates to managing long-term condition(s)
- Exploring beliefs and boundaries
- Insight and awareness of the drama triangle and what impact this can have
- Exploring each of the core coaching skills (open questions, empathy, value of silence, reflection, recognising change)
- Using confidence and/or importance scaling and practising how to embed use of these in coaching conversations
- Skills practice throughout using pair and group activities
- Understanding the flow of coaching conversations
- How to use appropriate resource tools to support conversations
- Using Microsoft Teams and Patient Knows Best platforms
- Awareness of appropriate signposting and increasing confidence in how to signpost well
- Goal setting and goal follow up

By the end of the course, volunteer coaches will be confident and competent to:

1. Understand their role, boundaries and how to seek help and guidance
2. Use technology to contact and engage with peers
3. Use health coaching conversational skills to work with peers on what matters to them, to support motivation for positive behaviour change to improve their health, wellbeing, and self-management of their condition
4. Be aware of local services and have the confidence to signpost to appropriate services
5. Know when and how to use the Health Connect Coaching Programme coordinators to support them in their role, and their peer on their journey.

Training will also include learning to use a range of behaviour change techniques which may include supporting peers to self-monitor, develop healthy habits, focus on past successes and set goals. Following successful completion of all training sessions and competence assessment by the coach trainers, coaches will be carefully matched to a peer. Matching will completed by the Programme Coordinators and will be based on criteria including: having a shared or similar health condition or symptoms, social deprivation (based on postcode), and other factors that peers feel are important to them which will be explored in an initial telephone conversation with the Coordinator. Volunteer coaches will be supervised and supported through monthly peer coaching group meetings and one-to-one supervision sessions with the coach coordinators as required. All coaches will complete a Disclosure and Barring Service (DBS) check prior to working with peers.

Outcomes

Primary Outcomes

The primary outcomes of this trial are feasibility outcomes.

Recruitment

Recruitment of peers and volunteer coaches will be calculated as follows:

Peer recruitment (%) = number of peers recruited/ potentially eligible cohort (indicated by the number of information packs distributed) x100

Coach recruitment (%) = number of volunteer coaches recruited/ potentially eligible cohort (indicated by the number of information packs sent or handed out) x100.

Retention and follow-up

Follow-up will be online. Peer retention and follow-up will be calculated as the proportion of peers completing all questionnaires at six months (post-intervention) and nine months (follow-up).

Coach retention will be calculated as the proportion of coaches who complete the training programme and coach at least one peer (defined as providing at least two coaching sessions).

Adherence

Adherence will be calculated as the number of sessions attended out of the total planned and mutually agreed coaching sessions (as long as this is at least two sessions).

Qualitative outcomes

We will report themes relevant to the experience of participating in the trial from peers, volunteer coaches and service provider staff, including feasibility of progressing to a full-scale trial. These will include experience of: referral and recruitment to the trial, randomisation, questionnaire completion, interview participation, and burden and reward for participation in the trial. In addition, reasons for not wanting to take part will be collated and reported where such information is provided on reply slips and/or in decliner interviews.

Secondary Outcomes

Peers will complete socio-demographic and health questionnaires at baseline only and the following health, wellbeing and resource use outcomes at baseline, post-intervention (six months) and follow-up (nine months) time points:

Patient Activation Measure (PAM®): This is a validated, 13-item licensed tool that has been extensively tested in many studies.[1] It measures the spectrum of knowledge, skills and confidence for managing health and healthcare.

Warwick Edinburgh Mental Wellbeing Scale (WEMWBS): This validated scale assesses mental wellbeing within the adult population using 14 questions.[21] The scale measures positive mental wellbeing in terms of both feeling good (hedonia) and functioning well (eudaimonia).

ICECAP-A: The ICECAP-A is a measure of capability in the adult population that can be used for economic evaluation.[22] It includes five items one for each domain: stability, attachment, autonomy, achievement and enjoyment. Each item includes four possible responses. A tariff

value for an overall state is calculated using an ICECAP algorithm and is used to calculate well-being adjusted life-years.

Health Confidence Score (HCS): The health confidence score is a short, generic, person-reported measure of people's perceived confidence in managing aspects of their own health and care. It has four items covering health knowledge, capability to self-manage, access to help and shared decisions.[23]

Long-Term Conditions Questionnaire (LTCQ): This 20-item questionnaire assesses outcomes in patients with either single or multiple LTCs (physical and/or mental health condition(s)) in health and social care contexts.[24] It measures across three broad concepts: impact of LTCs, experience of services and support, and self-care.

Resource use questionnaire: Details of health service utilisation including health, social and broader care provision and support (for example outpatient, A&E and GP visits, community care worker visits, voluntary sector support, and informal care) will be captured using a questionnaire developed by members of the research team for use in other trials.

Session Rating Scale 3.0 (SRS).[25] This is a four-item, client-completed measure of session experience.

Disease specific symptom measures

Participants will additionally be asked to complete one disease specific questionnaire. This will be selected based upon their clinical diagnosis from the five options below.

Brief Pain Inventory (BPI): The BPI includes 9 items and was developed to assess the severity of pain and the impact of pain on functioning.[26]

Multiple Sclerosis Impact Scale (MSIS-29v2): This is a 29-item condition specific measure of health-related quality of life, devised specifically for people with multiple sclerosis.[27]

The EULAR Psoriatic Arthritis Impact of Disease: PsAID9 for clinical trials (PsAID9): The 9-item PsAID is a questionnaire validated to assess the impact of Psoriatic Arthritis on patients' lives.[28]

The Bath AS Disease Activity Index (BASDAI): This 6-item questionnaire assesses the impact of the five major symptoms of Ankylosing Spondylitis.[29]

Rheumatoid Arthritis Impact of Disease (RAID) questionnaire: The rheumatoid arthritis impact of disease (RAID) questionnaire comprises seven domains of disease impact.[30]

Qualitative secondary outcomes

We will gather the views of participants and coaches about the volunteer coach training, matching process, intervention, coach-peer relationship, perceived impact on health and wellbeing and overall participation in the trial using a combination of semi-structured interviews, observations, and analysis of coaching plans. Purposive sampling will ensure interviewees are representative of the cohorts' range of demographic characteristics, degree of engagement with the programme, and in the case of coaches, will include coaches who coach a different numbers of peers and who use online or face-to-face delivery. We will also capture barriers to trial participation by interviewing decliners, volunteer coaches and peers who drop out. Peer, volunteer coach, staff and decliner interviews will explore the barriers and facilitators of set up and delivering the peer coaching service, its active ingredients in relation to the four elements of coaching outlined above and elements of the peer-coach relationship that facilitate behavioural change.

We will observe the training and monthly coaching supervision to understand, explore, and describe the intervention. Brief session notes will be recorded by the coach coordinators who lead the supervision sessions that will be used by the research team to summarise issues discussed. Analysis will be framed around a conceptual model of coaching adapted from Matthias and colleagues which includes motivation, strategies and finding what works.[31]

PPI statement

To ensure procedures and intervention delivery are acceptable and relevant to participants, they were developed with input from a Patient and Public Involvement (PPI) group that included people with lived experience of the targeted conditions (n=4). This was established and convened twice during the set-up phase of the trial. Key objectives of the PPI group include but are not limited to: trial materials development; questionnaire design and delivery; disease specific questionnaire selection; adaptations to intervention format, content, and delivery; data collection processes; interview topic guide development; and the minimising of burden and maximising of engagement and retention through identification of barriers and facilitators. Further consultation is planned to consider the interpretation of findings, dissemination strategy and the study's next steps. All PPI consultation has been, and will be completed in line with the NIHR guidelines, including financial reimbursement.

Data analysis

Quantitative

A detailed statistical analysis plan will be finalised before the trial database is locked. A CONSORT diagram will show information from screening, recruitment and follow-up and feasibility outcomes will be summarised with recruitment and retention rates presented with 95% confidence intervals. All quantitative data for this feasibility trial is self-reported and outcomes will be used and scored in line with author guidance. PAM scores will be calculated using the algorithm from Insignia Health (https://www.insigniahealth.com/products/pam-survey). Feasibility outcomes will be summarised with recruitment and retention rates presented with 95% confidence intervals. Descriptive statistics will be presented for secondary outcomes at baseline, six and nine months by allocated group. Between group differences of the change in scores between baseline and each follow-up time point will be presented but no inferential analysis will be performed, in accordance with CONSORT guidance.[32]

Sample size estimation

To inform sample size estimation for a future trial, we will calculate the standard deviations of the secondary outcomes of patient activation, mental wellbeing and quality of life. To estimate plausible between group differences for a primary outcome in a future definitive trial, namely change in scores on key secondary outcome measures from pre- to post intervention, we will calculate the between group difference (with 95% confidence intervals) in change score between baseline and follow-up (nine months).

Qualitative

We will use thematic framework analysis[33] following the five steps of analysis (familiarisation, identifying a thematic framework, indexing, charting, and mapping and interpretation) to explore qualitative data with themes identified and discussed between a minimum of two researchers. The process will use a combination of inductive and deductive framing, using the conceptual model of the intervention as a guide. Analysis will be completed using NVivo Version 12 (QSR International Pty Ltd, 2018). PPI input will help clarify and interpret identified themes within the framework.

Progression criteria

At the end of this feasibility trial the following criteria, developed in line with Avery et al (2017) will be used to determine progression to a full trial application. We shall progress to a full trial application if minimum success criteria are achieved in key feasibility areas. These criteria will be discussed with the Trial Management Group (TMG) and Trial Steering Committee (TSC), but may include:

- Target peer population (n=60) plus sufficient coaches recruited within 9-month recruitment window (<60% stop, 60-80% discuss, 80+% go)
- Adherence (defined as attending at least two of the mutually agreed number of coaching sessions (which may range from two to 14 sessions) of participants randomised to coaching (<40% of peers attend stop, 40-60% discuss, 60%+ go)
- Completion of outcome measures (scored PAM at nine-month follow-up) (<60% stop, 60-80% discuss, 80+% go)

- Evidence to suggest efficacy i.e. that the coaching holds promise as an effective intervention (indicated by examination of the confidence intervals of the between group differences in PAM at nine months and qualitative data).

Any issues that arise during this feasibility trial will be discussed with our PPI group members to consider possible action. Changes may be implemented within this feasibility trial or be evident upon trial completion which will inform the feasibility, and optimum delivery, for a potential definitive trial.

ETHICS AND DISSEMINATION

Safety monitoring

Throughout the trial, all possible precautions will be taken to ensure participant safety and wellbeing. Experienced professional coaches will deliver the volunteer coaching training and will ensure that volunteer coaches are trained and supervised to an appropriate level in order to deliver the coaching independently and safely. All Adverse events (AEs) will be reported by participants to the health connect coaching coordinators via their volunteer coach. This information will be shared with the research team who will assess any relation to the intervention. All serious adverse events (SAEs) will be reported to the CI within 24 hours of identification and the trial sponsor will be informed. All AEs and SAEs will be reported to the TMG on a monthly basis. In addition, a summary of this information will be shared with the TSC every six months.

Data management and monitoring

Confidentiality

Any identifiable information will be stored in a shared drive on TSDFT computers. All self-reported data will be collected via Jisc platform (https://www.onlinesurveys.ac.uk/). This anonymised data will be exported to and stored on a password protected and encrypted University computer. Interview recordings will be transcribed with any identifiable information removed. The recordings will be destroyed after transcription and the transcripts containing non-identifiable information will be retained. At the end of the trial all anonymized research information held on University computers will be returned to the sponsor (NHS trust) for storage for a minimum of five years. All information will be handled in compliance with the General Data Protection Regulations (2018).

Data monitoring

Data will be managed independently from the Sponsor and research funder. As this is a feasibility trial a Data Monitoring Committee has not been deemed necessary, as there will be insufficient data to establish benefits or harms of the intervention worthy of invoking early stopping rules.

Trial management and oversight

Two committees are involved in the set up and management of this trial.

The **Trial Management Group** comprises the university research team and members of the NHS Trust peer coaching service. It will meet monthly throughout the course of the trial via web-based platforms such as Microsoft Teams or face-to-face should COVID-19 restrictions allow. The group is responsible for development of the protocol and other trial documentation and ensuring smooth and safe running of the trial.

The Trial Steering Committee is made up of an independent chair, an independent statistician, a person with lived experience and an independent health economist. The role of the group is to provide overall supervision for the trial on behalf of the Sponsor and Funder and to ensure that the trial is conducted according to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. The group will continue to meet twice a year across the trial timeline.

Post-trial care

Participants in the control arm will be offered priority access to the intervention after final data collection has taken place. All participants will have access to their usual health care as routine practice.

Dissemination

Results from this feasibility trial will be shared directly with participants once they are available. In addition, results will be presented at local, regional, and national conferences. Further, the protocol and trial findings will be published in an open access journal and a final report will be presented to the funders and sponsor.

Trial registration

This trial is registered with the ISRCTN. ISRCTN12623577

Protocol version 1.0, 24/08/2021

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This work is funded by Torbay Medical Research Fund grant number project 137. The Funder has no role in trial design, conduct, data analyses and interpretation, manuscript writing, or dissemination of results.

Roles and Responsibilities

Dr Agne Straukiene (AS) is the chief investigator (CI) of the trial. Dr Julian Elston (JE) is the research manager. Dr Wendy Clyne (WC) and Dr Tom Thompson (TT) advise on trial methodology and conduct. Dr Joanne Hosking (JH) is the trial statistician. AS, JE, WC, TT and JH were responsible for trial design. Rachel Dennett (RD) is the trial co-ordinator. Helen Davies-Cox, Krystina Bones and Olivia Weight are responsible for the clinical delivery of the peer coaching service. Each of the named authors are members of the TMG and have contributed to the writing of this protocol.

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Competing interests

The authors declare no conflicts of interest.

Figure legends

Figure 1: Volunteer peer coaching logic model

Figure 2: Trial flow diagram: volunteer coach

Figure 3: Trial flow diagram- Peer

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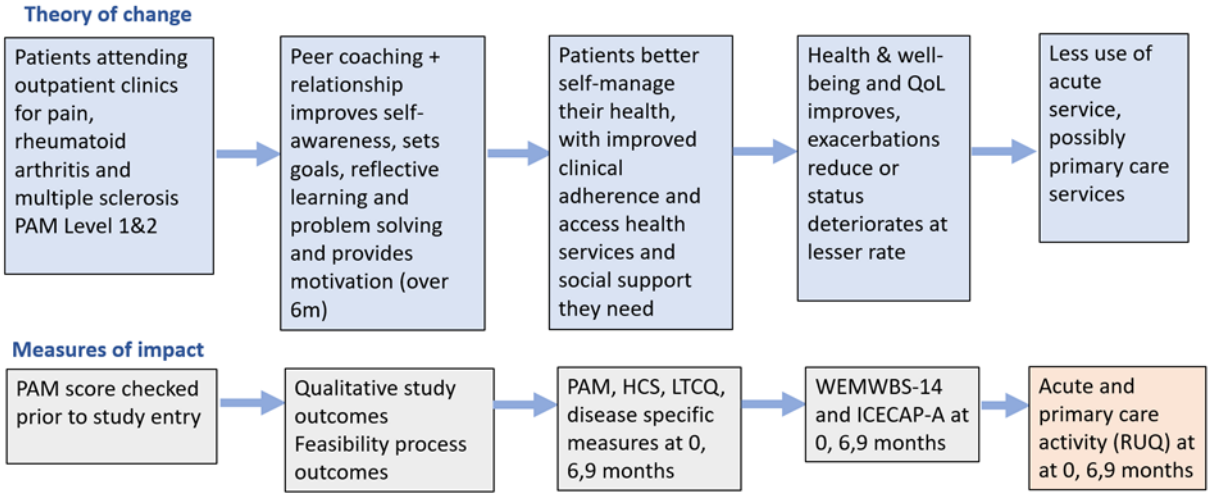
Figure 1: Volunteer peer coaching logic model



Abbreviations: PAM: Patient Activation Measure, m: months, QoL: Quality of Life, HCS: Health Confidence Score, LTCQ: Long-Term Conditions Questionnaire, WEMWBS: Warwick Edinburgh Mental Wellbeing Scale, ICECAP-A: ICEpop CAPability measure for Adults, RUQ: Resource use questionnaire

Figure 2: Trial flow diagram: volunteer coach

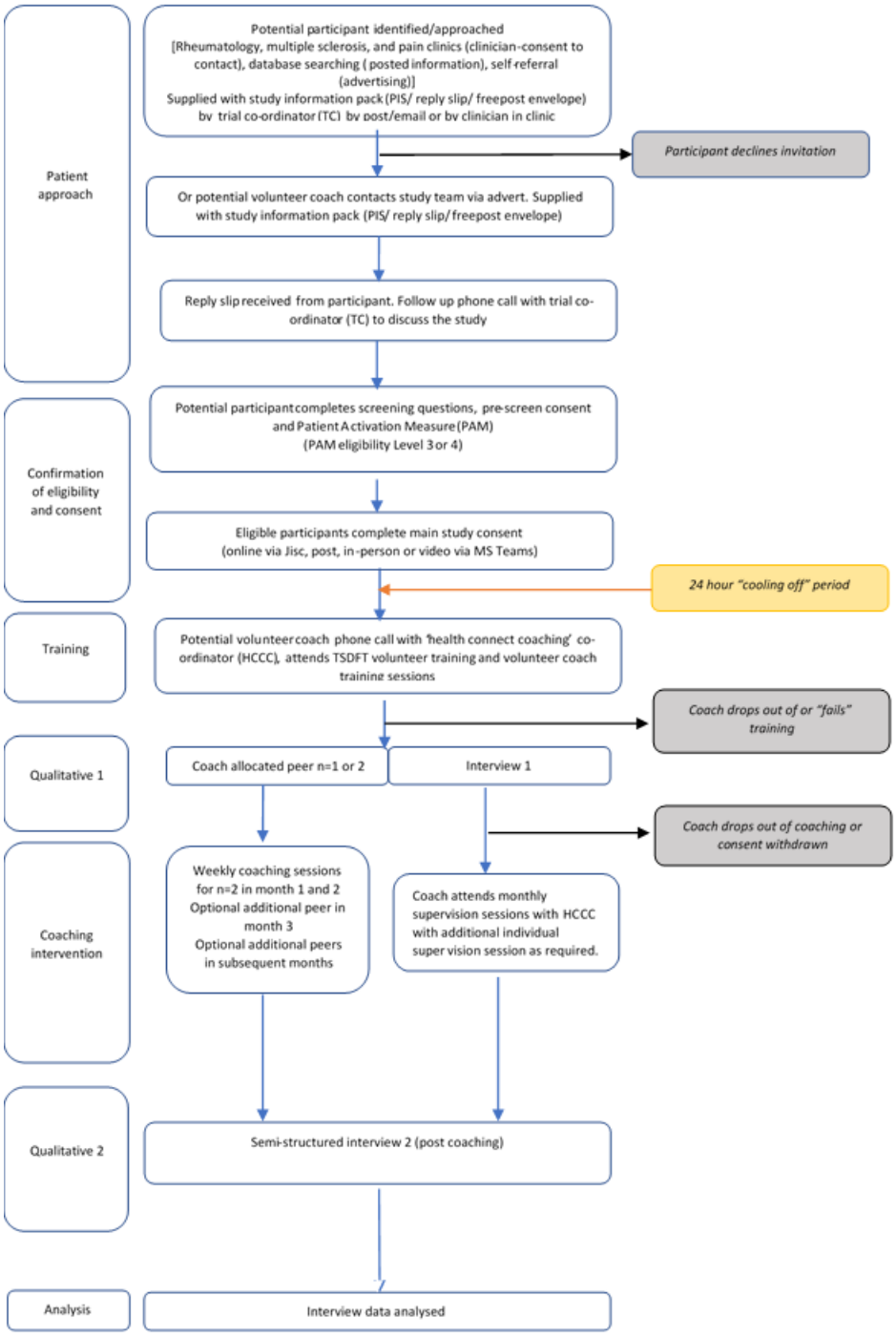
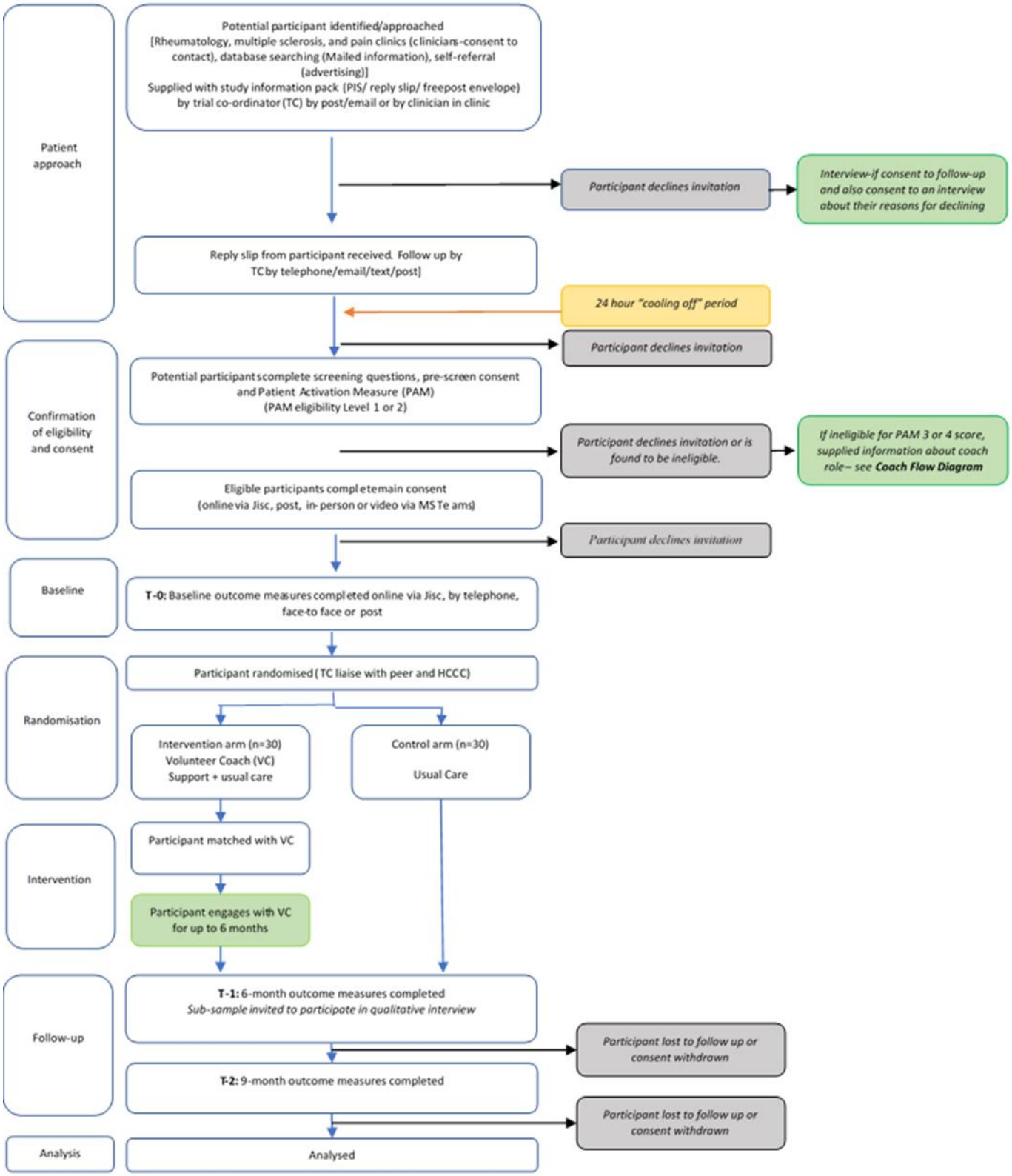


Figure 3: Trial flow diagram- Peer



Torbay Medical Research Fund

Information Sheet for Peers:

PEER CONNECT: Coaching Peers with Long Term Conditions

We would like to invite you to take part in a research study being conducted by the University of Plymouth and Torbay and South Devon NHS Foundation Trust. Before you decide whether to take part, it is important for you to understand why the study is being done and what it will involve. This information sheet tells you about the study. Please take time to read it carefully and discuss it with others if you wish. If there is anything that is unclear, or if you would like more information, please ask us. Your participation in this study is entirely voluntary.

Summary

NHS England estimates that 25-40% of patients have poor knowledge of their condition and poor skills and confidence to manage their health and wellbeing (termed here as low activation). People with less confidence and skills to manage their health condition are more likely to have unmet health needs, delay seeking healthcare and need emergency care. Peer coaching is a potential intervention that may help people to develop skills and confidence to manage their health but to date no research studies have been conducted in this group of patients.

Torbay and South Devon NHS Foundation Trust are funding a new volunteer peer coaching service for people with long term conditions and low activation attending outpatient services at Torbay and South Devon NHS Foundation Trust. Volunteer coaches will be trained by the Trust and will be responsible for coaching someone (referred to as a peer) over a six-month period, meeting for short conversations lasting from 15 minutes to up to an hour. It is likely that there will be one session per week for the first two months, followed by fortnightly sessions for two months and then monthly sessions for the final two months, totalling 14 sessions although this will be flexible. Coaching will be provided in a COVID-19 secure environment either on-line, by telephone or face-to-face. This research study is focused on people from rheumatology, chronic pain, and multiple sclerosis clinics.

People who would like to be part of this research as peers will be randomly assigned to one of two groups (using a process similar to tossing a coin). One group will receive the coaching and the other group will access their usual care. At the end of the nine months of being in the study those individuals in the usual care group will be offered the coaching.

As part of the study, peers (you) may be asked if a researcher can ask you about your experiences of being coached, your relationship with your coach and any impact it may have had on your health and well-being.

Why have I been chosen?

You have been chosen to take part because at a recent clinic appointment you may have suggested that you find managing your long-term health condition challenging. Alternatively, you may have seen our advert and have asked to find out more.

Do I have to take part?

No, you do not have to take part. It is your decision whether to take part or not. If you decide not to take part your usual healthcare will not be affected in any way.

What will happen if I take part?

If you decide you would like to take part, we will firstly contact you by phone or email to discuss the research study and ask you to sign a consent form agreeing to us asking you some questions to see if you would be eligible to be coached. This will include completing the Patient Activation Measure (PAM) questionnaire. If you are eligible, you will then be asked to sign another consent form to take part in the main study. You will be given signed copies of the consent forms for your own records. Next, we will ask you to complete some questionnaires about your health and wellbeing. After this we will tell you which group you are in. If you are in the coaching group, we will discuss our “matching” process with you and ask if you have any preferences before allocating you a coach. If you are in the usual care group you will be encouraged to continue to use your healthcare team as needed. After six months and again three months later we will ask you to complete the health and wellbeing questionnaires again. In addition, following the coaching we may ask if we can interview you to discuss your experiences. We will ask you to consent specifically to this interview (discussion) which will be recorded and then transcribed and anonymised.

What will happen next?

If you are interested in the study, please contact us using the information at the end of the sheet or by completing and sending back the reply slip. We will then contact you to discuss the study further.
If you are not interested in taking part in the study after reading this information sheet but would be happy to share your reasons why, please complete as indicated and return the reply slip.

Will any expenses be paid?

You will be offered £20.00 for completing the questionnaires at each of the three time points; the beginning, after the six months coaching and three months later. It is likely that interviews will take place on a web-based platform such as zoom and as such no payment is offered. If interviews are in-person, participants will be reimbursed for travel costs in-line with NIHR recommendations.

What are the possible disadvantages and risks of taking part?

It is possible that interpersonal issues may arise between you and your coach. Should this occur both parties will be encouraged to report such issues to the coaching co-ordinator and alternative coaching arrangements will be made if necessary. It is possible that coaches may offer inaccurate advice which could be detrimental to how you manage your condition. To try and ensure this does not happen, coaches will be trained to recognise boundaries to their role and limitations of their own knowledge. Any uncertainties will be addressed through regular supervisory meetings with the coordinator. To ensure the safety of you and your coach, the coach training will include elements of safeguarding, data protection and study reporting procedures. In addition, all coaches will have completed a DBS (Disclosure and Barring Service) check prior to working with you.

What are the possible benefits of taking part?

We cannot guarantee any direct benefit to you taking part in this study. It is hoped however, that taking part in the coaching will enhance your knowledge, skills, and confidence to manage your health more effectively.

How will we use information about you?

We will need to use information from you and your clinical team for this research project. This information will include your name, date of birth, contact details, diagnoses, GP and consultant names and contact details. Some members of the research team will use this information to do the research or to check your records to make sure that the research is being done properly (this may include the authorities governing UK research). Other members of the research team who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique code number instead, so you cannot be identified. We will keep all information about you safe and secure. Your name and contact information will be stored on Torbay and South Devon NHS Trust computers. This will be kept separate from the other information you supply during the project which will be stored anonymously with your unique code on a password protected and encrypted University of Plymouth

computer. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. Anonymous data collected from this study may be used to inform and support future research by the direct research team and by other researchers, including Insignia Health. As this data would be anonymised and shared using secure methods of data transfer, it would not be possible to identify you as a study participant. At the end of the study all research information held on University of Plymouth computers will be returned to the sponsor (Torbay and South Devon NHS Foundation Trust) who will store it for a minimum of 5 years. All information will be handled in compliance with the General Data Protection Regulations (2018).

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or by sending an email to peerconnect@plymouth.ac.uk. The NHS trust data protection officer can be contacted by e-mail: dataprotection.tsdft@nhs.net. Telephone number 01803 654868.

What will happen to the results of the research study?

We will work with people with long term health conditions to ensure that the anonymised findings are publicised as widely as possible and, if they are favourable, that a grant to conduct a multi-centre randomised controlled trial is submitted to the National Institute of Health Research (NIHR). We will publish the findings in scientific articles as well as in magazines that are read by the public and people with long term conditions. We will also present the findings at local (Torbay), regional and national meetings and at scientific conferences. A lay summary of the study findings will be made available to you at the end of the study. We will therefore keep your contact details until the summary is available.

Who is organising the research?

The study is sponsored by and taking place at Torbay and South Devon NHS Foundation Trust in collaboration with a team of researchers from the University of Plymouth. Dr Agne Straukiene (consultant neurologist) is the chief investigator for the study. Her contact details are below.

Who has funded the research?

The study has been funded by Torbay Medical Research Fund, a local charity.

Who has reviewed the study?

The study has been reviewed by the Health Research Authority's (HRA) NHS Research Ethics Committee (REC), the HRA Approval programme and University of Plymouth REC. It has also received local approval from Torbay and South Devon NHS Foundation Trust.

What if there is a problem?

In the first instance please contact Dr Agne Straukiene using the details at the end of this form. If your concern is not resolved, you can use the normal National Health Service complaints mechanisms. The Patient Advice and Liaison Service (PALS) are there to help. If you have any concerns or complaints about the Ethical conduct of this study, please contact the Research Administrator, Faculty of Health Ethics Committee, John Bull Building. Tamar Science Park, Research Way, Plymouth, Devon, PL68BU, Email: FOHEthics@plymouth.ac.uk.

Patient Advice and Liaison Service

Feedback and Engagement Team

Torbay and South Devon NHS Foundation Trust. Torbay Hospital, Lowes Bridge

Torquay TQ2 7AA. Telephone: 01803 655838. Email: tsdft.feedback@nhs.net

Contact for further information

Should you require any further information or have any further questions please contact;

Chief Investigator: Dr Agne Straukiene, MBChB, MMed, MRCP (London)

Consultant Neurologist, Department of Neurology, Torbay and South Devon NHS Foundation Trust, Lowes Bridge, Torquay, TQ2 7AA Secretary: 01803-654827, email: agne.straukiene@nhs.net

Or the trial study team email peerconnect@plymouth.ac.uk

Thank you for reading this information sheet

UNIVERSITY OF PLYMOUTH Faculty of Health
Torbay Medical Research Fund
Torbay and South Devon NHS Foundation Trust

Information Sheet for Volunteer Coaches

PEER CONNECT: Peer Coaching for Long-Term Conditions

We would like to invite you to take part in a research study being conducted by the University of Plymouth and Torbay and South Devon NHS Foundation Trust. Before you decide whether to take part, it is important for you to understand why the study is being done and what it will involve. This information sheet tells you about the study. Please take time to read it carefully and discuss it with others if you wish. If there is anything that is unclear, or if you would like more information, please ask us. Your participation in this study is entirely voluntary.

Summary

NHS England estimates that 25-40% of patients have poor knowledge of their condition and poor skills and confidence to manage their health and wellbeing (termed here as low activation). People with less confidence and skills to manage their health condition are more likely to have unmet health needs, delay seeking healthcare and need emergency care. Peer coaching is a potential intervention that may help people to develop skills and confidence to manage their health but to date no research studies have been conducted in this group of patients.

Torbay and South Devon NHS Foundation Trust are funding a new volunteer peer coaching service for people with long-term conditions with low activation attending outpatient services. People reporting high levels of knowledge, skills, and confidence to manage their condition (high activation) are being trained to provide the coaching. This research study is focused on people from rheumatology, chronic pain, and multiple sclerosis clinics.

As a volunteer coach you will receive eight group training sessions via an online platform, each lasting 90 minutes (with a break). There will be two sessions a week for four consecutive weeks. Training will total a minimum of 15 hours and will include homework activities, practical sessions, and on-line training modules. Learning will include evidence-based ways to support someone change behaviour to improve their health and well-being, motivational strategies and communication techniques. In addition, you will have opportunities to practise your coaching skills and receive regular supervision through monthly group and/or individual sessions with the coach coordinators. Once you and the team feel you are ready to start coaching you will be matched with someone who would like to be coached (referred to

as a peer). You will then be encouraged to meet together for short, focused conversations lasting from 15-60 minutes up to 14 times over a six-month period. These sessions will take part in a COVID-19 secure environment either on-line, by telephone or face-to-face if safe to do so. There will be opportunity to coach more than one peer during the study if you would like to do so. Prior to starting the coach training, all potential coaches will need to complete the Trust's mandatory volunteer training and undergo a Disclosure and Barring Service (DBS) check.

This is a feasibility study; a small study run to see if our research works in practice and if the peer coaching is acceptable to the people involved. As part of the process we are interviewing a number of people who train to be coaches to find out their experiences of being a coach, their relationship with their peer(s) and any impact coaching may have had on their health and well-being. If you are selected for this part of the study we will ask you to sign a separate consent form. These individual interviews (lasting up to an hour) will be recorded.

Why have I been chosen?

You have been chosen to take part in this research because you report to be managing your condition well and may like to train to be one of the volunteer coaches.

Do I have to take part?

No, you do not have to take part. It is your decision whether to take part or not. If you decide not to take part your usual healthcare will not be affected in any way.

What will happen if I take part?

If you decide you would like to take part we will firstly contact you by phone or email to discuss the research study and ask you to sign a consent form agreeing to us asking you some questions to see if you would be eligible to be a coach. This will include completing the Patient Activation Measure (PAM) questionnaire. If you are eligible you will then be asked to sign another consent form to take part in the main study. You will be given signed copies of the consent forms for your own records. Coaches will then receive volunteer training and peer coaching training from the Trust as detailed above.

What will happen next?

If you are interested in the study please contact us using the information at the end of the sheet or by completing and sending back the reply slip and we will contact you to discuss it further.

Will any expenses be paid?

Being a peer coach is a voluntary role therefore there is no payment. It is likely that interviews will take place on a web-based platform such as Zoom or Microsoft Teams and as such no payment is offered. If interviews are in-person, participants will be reimbursed for travel costs in-line with NIHR recommendations.

What are the other possible disadvantages and risks of taking part?

It is possible that providing coaching or discussing your experiences of coaching may cause you emotional distress. If this does occur we will ensure you have the opportunity to discuss your experiences further with someone from the peer coaching service.

What are the possible benefits of taking part?

We cannot guarantee any direct benefit to you taking part in this study. It is possible that training to be a coach and talking about your experiences of coaching will enhance your own knowledge, skills or confidence for managing your health and you may experience other positive benefits from contributing to research and service development processes.

How will we use information about you?

We will need to use information from you and your clinical team for this research project. This information will include your name, date of birth, contact details, diagnosis, GP and consultant names and contact details. Some members of the research team will use this information to do the research or to check your records to make sure that the research is being done properly (this may include the authorities governing UK research). Other members of the research team who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique code number instead, so you cannot be identified. We will keep all information about you safe and secure. Your name and contact information will be stored on Torbay and South Devon NHS Trust computers. This will be kept separate from the other information you supply during the project which will be stored anonymously with your unique code on a password protected and encrypted University of Plymouth computer. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. Anonymous data collected from this study may be used to inform and support future research by the direct research team and by other researchers, including Insignia Health. As this data would be anonymised and shared using secure methods of data transfer, it would not be possible to identify you as a study

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Consultant Neurologist, Department of Neurology, Torbay and South Devon NHS Foundation Trust, Lowes Bridge, Torquay, TQ2 7AA

Secretary: 01803-654827, email: agne.straukiene@nhs.net

Or the trial study team email peerconnect@plymouth.ac.uk

Thank you for reading this information sheet

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry Page 23
	2b	All items from the World Health Organization Trial Registration Data Set N/A
Protocol version	3	Date and version identifier Page 23
Funding	4	Sources and types of financial, material, and other support Page 24
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors Pages 1 and 24
	5b	Name and contact information for the trial sponsor Page 24
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities Page 24
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21 for data monitoring committee)Page 23
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention Page 4-6
	6b	Explanation for choice of comparators page 10
Objectives	7	Specific objectives or hypotheses page 6

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) page 7
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained page 8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) page 8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered pages 10-13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) pages 10-13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) pages 10-13
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial pages 10-13
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended pages 13-18
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) Page 9
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations page 19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size pages 8-9
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions page 9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned page 10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions page 9 and figure 3
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how page 10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial N/A
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol pages 14-18
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols pages 14,15,17
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol page 22
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol page 19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) N/A

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed page 22
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct page 21
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor pages 22-23

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval page 1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) Page 9
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial page 22
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site page 25
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators page 22
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation page 23

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions page 23
	31b	Authorship eligibility guidelines and any intended use of professional writers N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code N/A
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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Protocol for a pragmatic feasibility randomised controlled trial of peer coaching for adults with long term conditions: PEER CONNECT

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Title: Protocol for a pragmatic feasibility randomised controlled trial of peer coaching for adults with long term conditions: PEER CONNECT

Rachel Dennett[1,2] 0000-0003-0400-0502

Tom Thompson[2] 0000-0002-6366-9743

Wendy Clyne [2,3] 0000-0003-1523-700

Agne Straukiene [1]

Helen Davies-Cox[1]

Joanne Hosking [2]

Krystina Bones [1]

Olivia Weight [1]

Julian Elston[1, 2] 0000-0003-1378-5030

[1]Torbay and South Devon NHS Foundation Trust, Torbay, UK

[2]Faculty of Health, University of Plymouth, Plymouth, UK

[3]NIHR Research Design Service (RDS) South West, UK

Corresponding author Rachel Dennett rachel.dennett@plymouth.ac.uk

ABSTRACT

Introduction

Patients with low levels of knowledge, skills, and confidence to manage their health and wellbeing (activation) are more likely to have unmet health needs, delay seeking healthcare, and need emergency care. NHS England estimates that this may be applicable to 25-40% of patients with long-term health conditions. Volunteer peer coaching may support people to increase their level of activation. This form of intervention may be particularly effective for people with low levels of activation.

Methods and analysis

This single site, two-arm randomised controlled trial has been designed to assess the feasibility of conducting a definitive trial of volunteer peer health and wellbeing coaching for people with long-term health conditions (multiple sclerosis, rheumatoid arthritis or chronic pain) and low activation. Feasibility outcomes include recruitment and retention rates, and intervention adherence. We will measure patient activation, mental health and wellbeing as potential outcomes for a definitive trial. These outcomes will be summarised descriptively for each time point by allocated group and help to inform sample size calculation for the definitive trial. Criteria for progression to a full trial will be used.

Ethics and dissemination

Ethical approval has been granted by the London - Surrey Research Ethics Committee, reference 21/LO/0715. Results from this feasibility trial will be shared directly with participants, presented at local, regional, and national conferences and published in an open access journal.

Strengths and limitations of this trial

- It specifically targets patients with low levels of patient activation
- It utilises a novel, co-designed, volunteer peer coaching intervention for out-patients with long-term conditions based on an evidence-based and manualised training programme delivered online
- The research team includes academics, clinical service members and public contributors
- As a single site study the transferability of the trial's findings to other sites may be limited

INTRODUCTION

NHS England estimates that 25-40% of patients in England have low patient activation, defined as poor knowledge, skills, and confidence to manage health and wellbeing (Level 1 or 2 on the Patient Activation Measure (PAM)).[1] These patients are more likely to have unmet health needs, delay seeking healthcare, and need emergency care. Activation level is a modifiable factor, and it is likely that people with low activation have most to gain from an intervention designed to increase patient activation levels.[2] Supporting self-management in people with a health condition is one of six key components of the National Health Service (NHS) Personalised Care Model (PCM) to address low activation.[3] The PCM focuses on an individual's strengths and assets alongside working towards improvements in health conditions based on a 'what matters to me' approach.

One emerging approach from the literature to support self-management is health and wellbeing coaching.[4] Nationally, programmes have been developed primarily to support patients with lifestyle changes.[5] These recommend health professionals deliver coaching alongside their clinical work. However, national roll out and adoption of these programmes has been slow, which may be in part due to increasing demand on services and lack of resources due to stagnating budgets.[6] An alternative approach to staff delivery of coaching services is to involve patients with lived experience as coaches (peer coaches) especially if they are highly activated (PAM Level 3 and 4). There is an expanding body of research exploring the effectiveness of peer coaching provided via a range of delivery modes; in-person[7, 8]; telephone[9, 10] and digital.[11] Recent randomised controlled trials of peer coaching have included people with diabetes[9, 12, 13] and chronic pain.[8, 14, 15] These studies have demonstrated improvements in perceived physical activity (PA)[9] , quality of life (QoL)[9, 13],

pain[9] and depression.[12, 13] In contrast, Matthias and colleagues reported no statistically significant between-group differences at six (estimate(SE) 0.01 (0.23), CI(-0.45,0.46)) or nine-months (estimate(SE) 0.07 (0.24), CI(-0.40,0.54)) following their effectiveness trial of a peer coach-delivered pain self-management intervention versus controls who received a class on pain and pain self-management.[8] However, several trials have reported barriers to implementing this kind of intervention which guides towards methods to minimise or overcome potential barriers.

A number of studies have highlighted potential challenges of peer coaching such as coach wellbeing, [14] low intervention adherence and high drop-out rates.[8, 9, 13] A recent feasibility RCT of peer mentorship for people with osteoarthritis in the UK reports a mixed picture with challenges in matching coaches to peers and difficulties with coach retention alongside positive reports of coach enjoyment and satisfaction.[7, 16] We have not located any studies of peer coaching that have targeted peer coaching interventions at patients reporting low levels of activation. People with low levels of activation stand to benefit most from an intervention designed to improve confidence, problem solving and ability to manage their health care and wellbeing.[2] This may in turn impact use of health and social cares resources, and could feasibly be delivered by peers (others with long term conditions) with high levels of activation to negate the issues of resource within the NHS.

This paper describes the trial protocol for the PEER CONNECT study, a two-arm randomised controlled feasibility trial of peer coaching for people receiving out-patient care for one of three long-term health conditions; multiple sclerosis, rheumatoid arthritis or chronic pain. The peer coaching service will only be offered to people with low levels of patient activation. It provides up to 14 coaching sessions delivered over six months which decrease

in frequency over time. Volunteer peer coaches (confirmed to have high levels of activation) will attend a comprehensive training programme that follows a manualised coaching approach and includes independent and group learning sessions delivered online. In addition, they will receive regular individual and group supervision. The logic model for the intervention is illustrated in Figure 1.

Figure 1 here

Objectives

Our research question is:

Is it feasible to undertake a future definitive multi-centre RCT to determine the effectiveness of a targeted peer coaching intervention on the health and wellbeing of people with long-term health conditions and low activation attending outpatient services?

Our trial feasibility objectives are:

1. Are we able to identify, recruit, retain and follow-up eligible volunteer coaches and peers?
2. What is a sustainable number of peers per volunteer coach?
3. Are trial procedures acceptable to participants (peers and volunteer coaches)?
4. To estimate parameters needed to inform future sample size calculation
5. Are trial outcome measures acceptable to participants (peers)?
6. Does the trial demonstrate evidence to suggest that the coaching holds promise as an effective intervention?

Definitions

Within this paper the following key definitions are used:

- Peers: Participants eligible to receive coaching
- Volunteer peer coaches: Participants eligible to train to deliver coaching to peers

METHODS AND ANALYSIS

Study design

This research is a single site, two-arm, pragmatic randomised controlled feasibility trial. Eligible peers will be randomised 1:1 to either the intervention arm which includes (up to) 14 sessions of peer coaching over six months and their usual care, or the control arm who receive usual care only. Embedded within this feasibility study is a qualitative component that will include individual interviews with volunteer coaches and peers, clinic and peer coaching staff, and people who decline to take part in the interventional aspect of the study. All aspects of the trial protocol have been approved by the London - Surrey Research Ethics Committee, reference 21/LO/0715.

Participants

Eligibility criteria (peers and coaches)

Eligible participants will:

- Be aged 18 years or older (peers and volunteer coaches)

- Attend a rheumatology, pain or multiple sclerosis out-patient clinic (peers and volunteer coaches)
- Score PAM Level 1 or 2 (peers), PAM 3 or 4 (volunteer coaches)
- Be willing and able to engage in the six-month intervention (peers and volunteer coaches)
- Be willing and able to commit to undertaking assessments at baseline, six and nine months (peers).
- Have capacity to provide informed consent (peers and volunteer coaches)
- Have sufficient fluency in English to be able to engage with the intervention and trial material (peers and volunteer coaches)
- Not be participating in any other observational or interventional research trial

Recruitment

This trial aims to recruit 15 volunteer coaches and 60 peers to take part in the intervention. This feasibility sample size was selected by a team of experienced researchers and clinicians and was based upon predicted recruitment within time frame and resource, parameters of the population size, modelling of coach to peer matching and is in line with recommendations.[17] The sample size of 60 peers will allow overall retention rate to be estimated to within a 95% confidence interval of approximately ±13%. Coaches, peers, clinic and service delivery staff, and people who decline to take part in the study will also be invited to take part in the qualitative component of the research.

Recruitment of volunteer coaches and peers

Potential volunteer coaches and peers will be recruited from the multiple sclerosis, rheumatology and chronic pain out-patient clinics at a single NHS Trust (Torbay and South Devon NHS Foundation Trust (TSDFT)). In addition, the relevant study information will be sent to patients with a recorded PAM score on the clinical team's database. Patients known to multiple sclerosis, rheumatology and chronic pain clinics may also respond directly to adverts placed at a range of healthcare and community venues. Recruitment is planned to commence in November 2021 and continue for six months. Figures 2 and 3 indicate the research journey of eligible participants. Following initial telephone screening potential participants will provide consent to complete the PAM to confirm eligibility as a volunteer coach or peer.

Figures 2 and 3 here

Consent

Participants will be offered a choice of four options for providing informed consent:

1. In-person signed form with scanned copy stored electronically on a TSDFT secure drive.

2. Video-recorded using MS Teams and stored securely as above.

3. Completed via Jisc (https://www.onlinesurveys.ac.uk/) with exported record stored securely as above.

4. Postal signed consent form, scanned on receipt and stored as above.

Randomisation

Following baseline data collection, eligible peers will be randomised to either the intervention or control arm on a 1:1 ratio using random permuted blocks, stratified by out-patient clinic. The randomisation list will be generated and stored by a statistician not involved in the trial, and allocation will be accessed through a web-portal hosted by the University of Plymouth Peninsula Clinical Trials Unit.

Blinding

Blinding of participants will not be possible due to the nature of the intervention. Due to restricted capacity not all members of the research team will be blinded. The trial statistician will be blinded to allocation.

Intervention and setting

Setting

All participants will be recruited from TSDFT, a district general hospital in the South West of the United Kingdom (UK).

Control arm

Usual care is defined as access to services and treatment provided as routine care, examples of which include attending out-patient clinic appointments, referral to therapies, and signposting to community or support services as required.

Intervention arm

The intervention includes up to 14 sessions with a volunteer coach delivered over six months. Sessions are expected to last from 15-60 minutes and will be provided in a COVID-19 secure environment either on-line, by telephone or face-to-face. A flexible framework for the coaching will be used to facilitate a personalised approach with a suggested format of one session per week for the first two months, followed by fortnightly sessions for two months and monthly sessions thereafter. Peers will be supported to produce a coaching plan with associated goals at the end of each session. A brief summary of the content, duration, and mode of coaching delivery will also be recorded. Missed planned sessions (non-attendance) will be recorded by the volunteer coach. In addition, peers will be asked to report any adverse events (AEs) they have experienced and rate their experience of being coached.

Volunteer coach training

Volunteer peer coach training will include eight structured 90-minute live sessions supported by interactive online learning tasks (homework). Training will be delivered by the TSDFT volunteer peer health and wellbeing coaching service, the 'Health Connect Coaching Programme'. Sessions will draw on evidence-based behavioural change methods[18], motivational strategies[19], and communication techniques. The content will also draw on evidence-based materials to improve health and wellbeing such as Making Every Contact Count (MECC)[20], Five Ways to Well Being[21], and NHS health coaching programmes.[5] The intervention will emphasise:[22]

- A patient-centred approach where patients determine their goals
- Active learning or self-discovery

- A problem-solving focus to work towards goals
- Regular peer feedback on implementing the coaching plan

Training will initially be completed virtually using Microsoft Teams, with a view to offer face-to-face training in the future should COVID-19 restrictions allow. Each 90-minute session will include a break. There will be two training sessions each week for four consecutive weeks. Training will total a minimum of 15 hours for each volunteer coach (12 hours of live sessions and around 3 hours homework) and will include practical sessions and on-line modules.

The training content covers:

- Background to personalised care and why it matters
- How this volunteer role has been developed and why
- Stages of behaviour change and how this relates to managing long-term condition(s)
- Exploring beliefs and boundaries
- Insight and awareness of the drama triangle and what impact this can have
- Exploring each of the core coaching skills (open questions, empathy, value of silence, reflection, recognising change)
- Using confidence and/or importance scaling and practising how to embed use of these in coaching conversations
- Skills practice throughout using pair and group activities
- Understanding the flow of coaching conversations
- How to use appropriate resource tools to support conversations

- Using Microsoft Teams and Patient Knows Best platforms
- Awareness of appropriate signposting and increasing confidence in how to signpost well
- Goal setting and goal follow up

By the end of the course, volunteer coaches will be confident and competent to:

1. Understand their role, boundaries and how to seek help and guidance
2. Use technology to contact and engage with peers
3. Use health coaching conversational skills to work with peers on what matters to them, to support motivation for positive behaviour change to improve their health, wellbeing, and self-management of their condition
4. Be aware of local services and have the confidence to signpost to appropriate services
5. Know when and how to use the Health Connect Coaching Programme coordinators to support them in their role, and their peer on their journey.

Training will also include learning to use a range of behaviour change techniques which may include supporting peers to self-monitor, develop healthy habits, focus on past successes and set goals. Following successful completion of all training sessions and competence assessment by the coach trainers, coaches will be carefully matched to a peer. Matching will completed by the Programme Coordinators and will be based on criteria including: having a shared or similar health condition or symptoms, social deprivation (based on postcode), and

other factors that peers feel are important to them which will be explored in an initial telephone conversation with the Coordinator. Volunteer coaches will be supervised and supported through monthly peer coaching group meetings and one-to-one supervision sessions with the coach coordinators as required. All coaches will complete a Disclosure and Barring Service (DBS) check prior to working with peers.

Outcomes

Primary Outcomes

The primary outcomes of this trial are feasibility outcomes.

Recruitment

Recruitment of peers and volunteer coaches will be calculated as follows:

Peer recruitment (%) = number of peers recruited/ potentially eligible cohort (indicated by the number of information packs distributed) x100

Coach recruitment (%) = number of volunteer coaches recruited/ potentially eligible cohort (indicated by the number of information packs sent or handed out) x100.

Retention and follow-up

Follow-up will be online. Peer retention and follow-up will be calculated as the proportion of peers completing all questionnaires at six months (post-intervention) and nine months (follow-up).

Coach retention will be calculated as the proportion of coaches who complete the training programme and coach at least one peer (defined as providing at least two coaching sessions).

Adherence

Adherence will be calculated as the number of sessions attended out of the total planned and mutually agreed coaching sessions (as long as this is at least two sessions).

Qualitative outcomes

We will report themes relevant to the experience of participating in the trial from peers, volunteer coaches and service provider staff, including feasibility of progressing to a full-scale trial. These will include experience of: referral and recruitment to the trial, randomisation, questionnaire completion, interview participation, and burden and reward for participation in the trial. In addition, reasons for not wanting to take part will be collated and reported where such information is provided on reply slips and/or in decliner interviews.

Secondary Outcomes

Peers will complete a socio-demographic and health questionnaire (including items such as diagnosis, time since diagnosis, co-morbidity, place of residence, level of mobility and occupation) at baseline. The following health, wellbeing and resource use outcomes will be completed at baseline, post-intervention (six months) and follow-up (nine months) time points:

Patient Activation Measure (PAM®): This is a validated, 13-item licensed tool that has been extensively tested in many studies.[1] It measures the spectrum of knowledge, skills and confidence for managing health and healthcare.

Warwick Edinburgh Mental Wellbeing Scale (WEMWBS): This validated scale assesses mental wellbeing within the adult population using 14 questions.[23] The scale measures positive mental wellbeing in terms of both feeling good (hedonia) and functioning well (eudaimonia).

ICECAP-A: The ICECAP-A is a measure of capability in the adult population that can be used for economic evaluation.[24] It includes five items one for each domain: stability, attachment, autonomy, achievement and enjoyment. Each item includes four possible responses. A tariff value for an overall state is calculated using an ICECAP algorithm and is used to calculate well-being adjusted life-years.

Health Confidence Score (HCS): The health confidence score is a short, generic, person-reported measure of people's perceived confidence in managing aspects of their own health and care. It has four items covering health knowledge, capability to self-manage, access to help and shared decisions.[25]

Long-Term Conditions Questionnaire (LTCQ): This 20-item questionnaire assesses outcomes in patients with either single or multiple LTCs (physical and/or mental health condition(s)) in health and social care contexts.[26] It measures across three broad concepts: impact of LTCs, experience of services and support, and self-care.

Resource use questionnaire: Details of health service utilisation including health, social and broader care provision and support (for example outpatient, A&E and GP visits, community

care worker visits, voluntary sector support, and informal care) will be captured using a questionnaire developed by members of the research team for use in other trials.

Session Rating Scale 3.0 (SRS).[27] This is a four-item, client-completed measure of session experience.

Disease specific symptom measures

Participants will additionally be asked to complete one disease specific questionnaire. This will be selected based upon their clinical diagnosis from the five options below.

Brief Pain Inventory (BPI): The BPI includes 9 items and was developed to assess the severity of pain and the impact of pain on functioning.[28]

Multiple Sclerosis Impact Scale (MSIS-29v2): This is a 29-item condition specific measure of health-related quality of life, devised specifically for people with multiple sclerosis.[29]

The EULAR Psoriatic Arthritis Impact of Disease: PsAID9 for clinical trials (PsAID9): The 9-item PsAID is a questionnaire validated to assess the impact of Psoriatic Arthritis on patients' lives.[30]

The Bath AS Disease Activity Index (BASDAI): This 6-item questionnaire assesses the impact of the five major symptoms of Ankylosing Spondylitis.[31]

Rheumatoid Arthritis Impact of Disease (RAID) questionnaire: The rheumatoid arthritis impact of disease (RAID) questionnaire comprises seven domains of disease impact.[32]

Qualitative secondary outcomes

We will gather the views of peers and coaches about the volunteer coach training, matching process, intervention, coach-peer relationship, perceived impact on health and wellbeing

and overall participation in the trial using a combination of semi-structured interviews, observations, and analysis of coaching plans. Purposive sampling will ensure interviewees are representative of the cohorts' range of demographic characteristics, degree of engagement with the programme, and in the case of coaches, will include coaches who coach a different numbers of peers and who use online or face-to-face delivery. We will also capture barriers to trial participation by interviewing decliners, volunteer coaches and peers who drop out. Peer, volunteer coach, staff and decliner interviews will explore the barriers and facilitators of set up and delivering the peer coaching service, its active ingredients in relation to the four elements of coaching outlined above and elements of the peer-coach relationship that facilitate behavioural change.

We will observe the training and monthly coaching supervision to understand, explore, and describe the intervention. Brief session notes will be recorded by the coach coordinators who lead the supervision sessions that will be used by the research team to summarise issues discussed. Analysis will be framed around a conceptual model of coaching adapted from Matthias and colleagues which includes motivation, strategies and finding what works.[33]

Patient and Public Involvement Statement

To ensure procedures and intervention delivery are acceptable and relevant to participants, they were developed with input from a Patient and Public Involvement (PPI) group that included people with lived experience of the targeted conditions (n=7, 2 women). Members of the group had either attended a TSDFT co-design event in 2019 and had continued to be part of the intervention development or were recruited from local condition-specific

support groups. The group was established and convened twice during the set-up phase of the trial. Key objectives of the PPI group include but are not limited to: trial materials development; questionnaire design and delivery; disease specific questionnaire selection; adaptations to intervention format, content, and delivery; data collection processes; interview topic guide development; and the minimising of burden and maximising of engagement and retention through identification of barriers and facilitators. Further consultation is planned to consider the interpretation of findings, dissemination strategy and the study's next steps. All PPI consultation has been, and will be completed in line with the NIHR guidelines, including financial reimbursement.

Data analysis

Quantitative

A period of five months has been allocated for data analysis, write up and dissemination. A detailed statistical analysis plan will be finalised before the trial database is locked. A CONSORT diagram will show information from screening, recruitment and follow-up and feasibility outcomes will be summarised with recruitment and retention rates presented with 95% confidence intervals. All quantitative data for this feasibility trial is self-reported and outcomes will be used and scored in line with author guidance. PAM scores will be calculated using the algorithm from Insignia Health (https://www.insigniahealth.com/products/pam-survey). Feasibility outcomes will be summarised with recruitment and retention rates presented with 95% confidence intervals. Descriptive statistics will be presented for secondary outcomes at baseline, six and nine months by allocated group. Between group differences of the change in scores between

baseline and each follow-up time point will be presented but no inferential analysis will be performed, in accordance with CONSORT guidance.[34]

Sample size estimation

To inform sample size estimation for a future trial, we will calculate the standard deviations of the secondary outcomes of patient activation, mental wellbeing and quality of life. To estimate plausible between group differences for a primary outcome in a future definitive trial, namely change in scores on key secondary outcome measures from pre- to post intervention, we will calculate the between group difference (with 95% confidence intervals) in change score between baseline and follow-up (nine months).

Qualitative

We will use thematic framework analysis[35] following the five steps of analysis (familiarisation, identifying a thematic framework, indexing, charting, and mapping and interpretation) to explore qualitative data with themes identified and discussed between a minimum of two researchers. The process will use a combination of inductive and deductive framing, using the conceptual model of the intervention as a guide. Analysis will be completed using NVivo Version 12 (QSR International Pty Ltd, 2018). PPI input will help clarify and interpret identified themes within the framework.

Progression criteria

At the end of this feasibility trial the following criteria, developed in line with Avery et al[36] will be used to determine progression to a full trial application. We shall progress to a full trial application if minimum success criteria are achieved in key feasibility areas. These criteria will be discussed with the Trial Management Group (TMG) and Trial Steering Committee (TSC), but may include:

- Target peer population (n=60) plus sufficient coaches recruited within 9-month recruitment window (<60% stop, 60-80% discuss, 80+% go)
- Adherence (a 'dose' of coaching is defined as attending at least two of the mutually agreed number of coaching sessions[37] (which may range from two to 14 sessions) of participants randomised to coaching (<40% of peers attend stop, 40-60% discuss, 60%+ go)
- Completion of outcome measures (scored PAM at nine-month follow-up) (<60% stop, 60-80% discuss, 80+% go)
- Evidence to suggest efficacy i.e. that the coaching holds promise as an effective intervention (indicated by examination of the confidence intervals of the between group differences in PAM at nine months and qualitative data).

Any issues that arise during this feasibility trial will be discussed with our PPI group members to consider possible action. Changes may be implemented within this feasibility trial or be evident upon trial completion which will inform the feasibility, and optimum delivery, for a potential definitive trial.

ETHICS AND DISSEMINATION

Safety monitoring

Throughout the trial, all possible precautions will be taken to ensure participant safety and wellbeing. Experienced professional coaches will deliver the volunteer coaching training and will ensure that volunteer coaches are trained and supervised to an appropriate level in order to deliver the coaching independently and safely. All Adverse events (AEs) will be reported by participants to the health connect coaching coordinators via their volunteer coach. This information will be shared with the research team who will assess any relation to the intervention. All serious adverse events (SAEs) will be reported to the CI within 24 hours of identification and the trial sponsor will be informed. All AEs and SAEs will be reported to the TMG on a monthly basis. In addition, a summary of this information will be shared with the TSC every six months.

Data management and monitoring

Confidentiality

Any identifiable information will be stored in a shared drive on TSDFT computers. All self-reported data will be collected via Jisc platform (https://www.onlinesurveys.ac.uk/). This anonymised data will be exported to and stored on a password protected and encrypted University computer. Interview recordings will be transcribed with any identifiable information removed. The recordings will be destroyed after transcription and the transcripts containing non-identifiable information will be retained. At the end of the trial all anonymized research information held on University computers will be returned to the sponsor (NHS trust) for storage on a TSDFT drive for a minimum of five years. As members

of the research team also hold honorary contracts with TSDFT no other data sharing agreements are necessary. All information will be handled in compliance with the General Data Protection Regulations (2018).

Data monitoring

Data will be managed independently from the Sponsor and research funder. As this is a feasibility trial a Data Monitoring Committee has not been deemed necessary, as there will be insufficient data to establish benefits or harms of the intervention worthy of invoking early stopping rules.

Trial management and oversight

Two committees are involved in the set up and management of this trial.

The **Trial Management Group** comprises the university research team and members of the NHS Trust peer coaching service. It will meet monthly throughout the course of the trial via web-based platforms such as Microsoft Teams or face-to-face should COVID-19 restrictions allow. The group is responsible for development of the protocol and other trial documentation and ensuring smooth and safe running of the trial.

The Trial Steering Committee is made up of an independent chair, an independent statistician, a person with lived experience and an independent health economist. The role of the group is to provide overall supervision for the trial on behalf of the Sponsor and Funder and to ensure that the trial is conducted according to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. The group will continue to meet twice a year across the trial timeline.

Post-trial care

Participants in the control arm will be offered priority access to the intervention after final data collection has taken place. All participants will have access to their usual health care as routine practice.

Dissemination

Results from this feasibility trial will be shared directly with participants once they are available. In addition, results will be presented at local, regional, and national conferences. Further, the protocol and trial findings will be published in an open access journal and a final report will be presented to the funders and sponsor.

Trial registration

This trial is registered with the ISRCTN. ISRCTN12623577

Protocol version 1.0, 24/08/2021

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This work is funded by Torbay Medical Research Fund grant number project 137. The Funder has no role in trial design, conduct, data analyses and interpretation, manuscript writing, or dissemination of results.

Contributorship Statement

AS, JE, WC, TT, JH, HDC developed the study. RD, AS, JE, WC, TT, JH, HDC, KB and OW are responsible for the conduct of the study. Each of the named authors contributed to the reporting of this work.

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Competing interests

The authors declare no conflicts of interest.

Figure legends

Figure 1: Volunteer peer coaching logic model

Figure 2: Trial flow diagram: volunteer coach

Figure 3: Trial flow diagram- Peer

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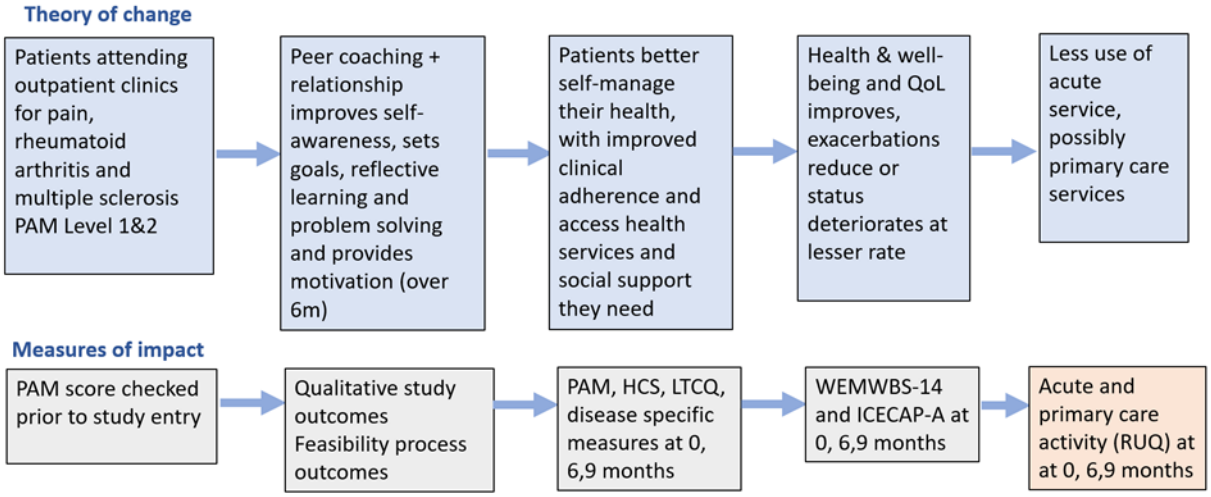
Figure 1: Volunteer peer coaching logic model



Abbreviations: PAM: Patient Activation Measure, m: months, QoL: Quality of Life, HCS: Health Confidence Score, LTCQ: Long-Term Conditions Questionnaire, WEMWBS: Warwick Edinburgh Mental Wellbeing Scale, ICECAP-A: ICEpop CAPability measure for Adults, RUQ: Resource use questionnaire

Figure 2: Trial flow diagram- Volunteer Coach

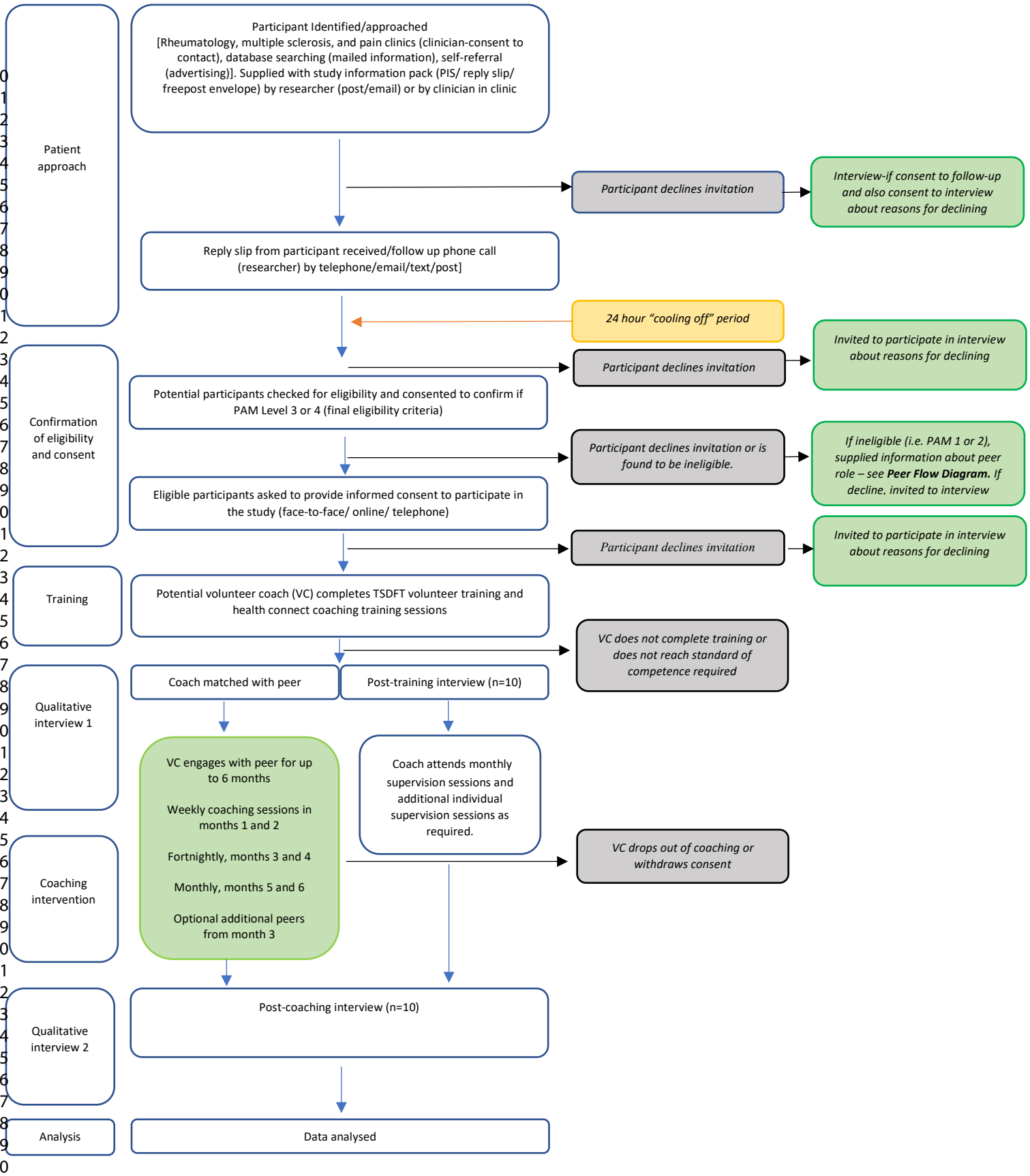
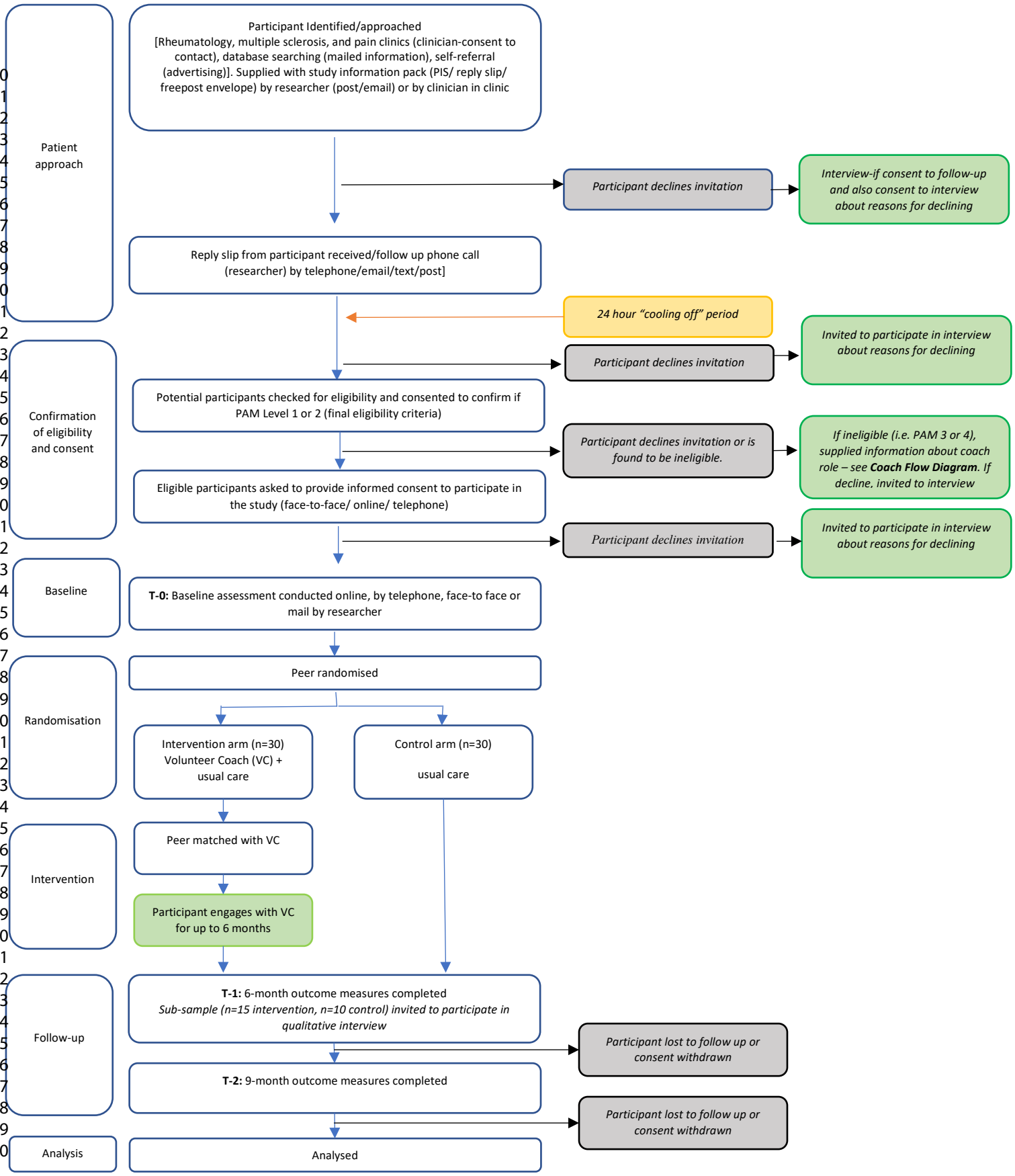


Figure 3: Trial flow diagram- Peer



SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym Page 1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry Page 23
	2b	All items from the World Health Organization Trial Registration Data Set N/A
Protocol version	3	Date and version identifier Page 23
Funding	4	Sources and types of financial, material, and other support Page 24
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors Pages 1 and 24
	5b	Name and contact information for the trial sponsor Page 24
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities Page 24
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21 for data monitoring committee)Page 23
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention Page 4-6
	6b	Explanation for choice of comparators page 10
Objectives	7	Specific objectives or hypotheses page 6

Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) page 7

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained page 8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) page 8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered pages 10-13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) pages 10-13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) pages 10-13
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial pages 10-13
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended pages 13-18
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) Page 9
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations page 19
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size pages 8-9

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions page 9
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned page 10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions page 9 and figure 3
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how page 10
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial N/A
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol pages 14-18
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols pages 14,15,17
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol page 22
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol page 19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) N/A

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed page 22
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct page 21
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor pages 22-23

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval page 1
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) Page 9
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial page 22
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site page 25
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators page 22
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation page 23

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions page 23
	31b	Authorship eligibility guidelines and any intended use of professional writers N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code N/A
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.