Work And Vocational advicE (WAVE)
in primary care: a randomised controlled trial

PROTOCOL

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SIGNATURE PAGE

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The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the research in compliance with the approved protocol, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Date: 05/OCT/2020

Signature:

Name (please print): Dr Gwenllian Wynne-Jones

Sponsor statement:

Where Keele University takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the Sponsor will serve as confirmation of approval of this protocol.

AMENDMENT HISTORY

Amendment No.	Protocol version no.	Effective date	Aspect of study subject to change	Details of changes made
		___/___/___ _		
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i) List of abbreviations

AI	Associate Investigator
CI	Chief Investigator
CRF	Case Report Form
CRN	Clinical Research Network
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
EQ5-D-5L	Euro Qol 5 Dimension 5 Level
GAD	Generalised Anxiety Disorder
GP	General Practitioner
GCP	Good Clinical Practice
GPPAQ	General Practice Physical Activity Questionnaire
HRA	Health Research Authority
HROC	Health Research Oversight Committee
ICD-10	International Classification of Diseases 10
HSCR QMS	Health and Social Care Research Quality Management System
MDC	Minimum Data Collection
MH	Mental Health
MSK	Musculoskeletal
NHS	National Health Service
NIHR	National Institute for Health Research
PHQ	Patient Health Questionnaire
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PPIE	Patient and Public Involvement and Engagement
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RTW	Return To Work
RTW-SE	Return To Work – Self Efficacy
RUG	Research User Group
SF12	Short Form 12 (questionnaire)
SME	Small and Medium Enterprise
SMS	Short Message Service
SOPs	Standard Operating Procedures
TMG	Trial Management Group
TSC	Trial Steering Committee
VSW	Vocational Support Worker
WPAI	Work Productivity and Activity Impairment Questionnaire

ii) Key contacts

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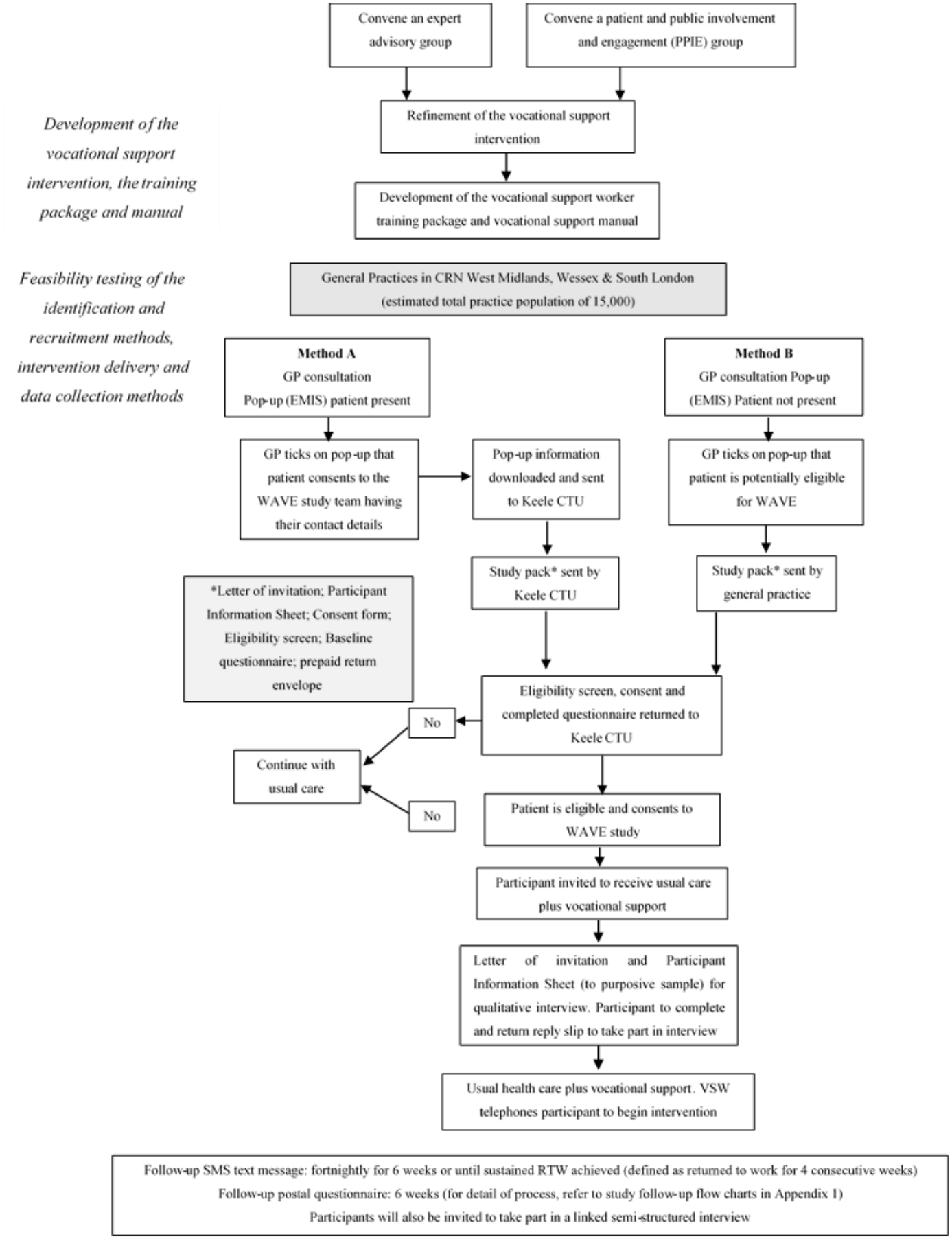
iii) Study summary

Study Title	Work And Vocational advicE (WAVE) in primary care: a randomised controlled trial
Internal Ref. Number (or short title)	WAVE Study
Study Design	Feasibility study followed by an internal pilot and randomised controlled trial (RCT) with full health economic analysis and linked qualitative interviews.
Trial Interventions (where applicable)	**Control arm:** Participants randomised to the control arm will continue to receive care as usual for their health and vocational needs. For most patients, this will comprise usual clinical care, without formal vocational advice. **Intervention arm:** Vocational support following a stepped care model based on the principles of case management in addition to usual primary care. Participants randomised to receive this arm of the trial will all be offered **Step 1**, contact by phone to undertake an assessment with a trained Vocational Support Worker (VSW) to identify obstacles to Return to Work (RTW) and support RTW planning. Those who require it will also be offered **Step 2**, face-to-face (in person or by videoconference) in-depth discussion of obstacles to RTW and further support for RTW planning. Those who require it will also be offered **Step 3,** contact by the VSW (with participant consent) with the participants' workplace (line manager). The frequency of contact will be individualised to the needs of participants and the offer of support continued until sustained RTW (defined as return to any work for at least 4 weeks) or until 6 months of absence, after which participants will be signposted to other services. The intervention is underpinned by a logic model describing the intervention content, anticipated mediators and outcomes.

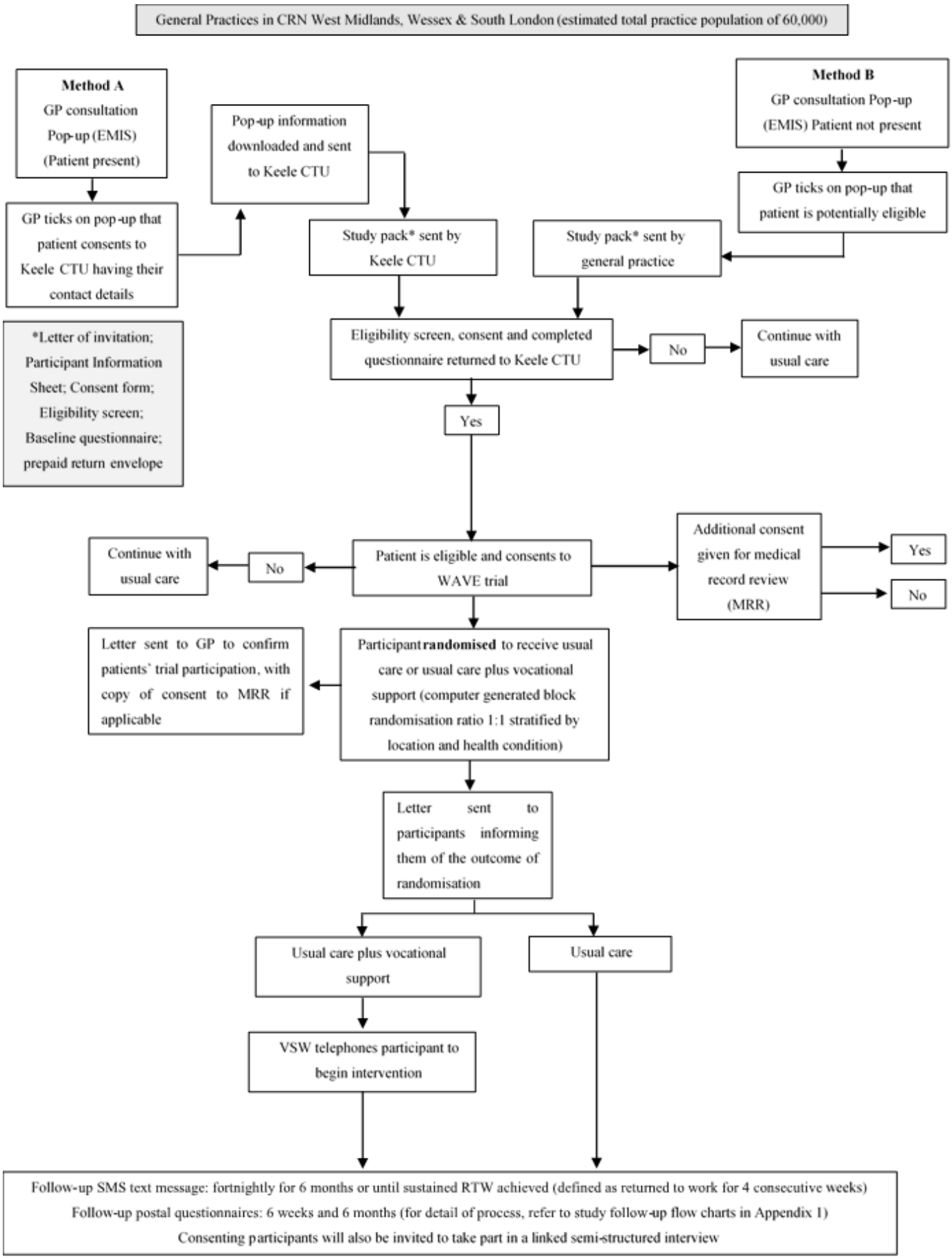
Trial Participants	Adults in paid employment, with a current work absence of at least 2 continuous weeks but not more than 6 months, who have received a fit note and can receive and respond to SMS text messages and communicate in English.	
Planned Sample Size	Feasibility phase: 30 participants to receive intervention. Internal pilot and main randomised trial: 720 participants randomised over 18 months. Interviews: up to 20 participants in the feasibility phase, up to 20 interviews with trial participants and up to 20 interviews with VSWs, general practitioners and employers in the RCT phase.	
Intervention duration	The intervention will continue to be offered until the participants achieve a sustained RTW (RTW for at least 4 weeks) or until they reach 6 months of absence.	
Follow up duration	6 months following randomisation.	
Planned Trial Period	Feasibility phase: May 2019 (including intervention development) to May 2021 (completion of analysis) RCT and internal pilot phase: May 2021 (trial set up) to March 2024 (completion of trial analysis).	
	Objectives	Outcome Measures
Feasibility phase (Including linked qualitative interviews)	To test the participants identification methods, patients' willingness to engage with the intervention and the fidelity of intervention delivery.	Examination of the numbers and proportions who are eligible and interested, who consent to participate, and who engage with the intervention, the level of intervention delivered i.e. steps reached, including number and duration of phone calls, face to face / video consultations and work-place contacts. Assessment of fidelity will be based on the content of the consultations participants have with the VSWs, achieved in two ways: (i) recording phone calls and face to face /video meetings between the VSWs and the participant (with participant consent); (ii) examining Case Report Forms (CRFs) completed by the VSWs detailing the content of the intervention delivered.
	To understand study participants' experiences of being invited to participate,	Interviews will be used to explore participants' views on being invited into the

	the delivery of the vocational support intervention and the usefulness of the intervention in supporting them to RTW.	feasibility study, how the intervention might have supported them in their RTW, and how the trial processes could be improved.
Internal pilot	To assess participant recruitment and intervention fidelity in those recruited in the first 4 months of RCT recruitment, and assess the follow-up rate for the primary outcome at 6 months in those participants.	(i) recruitment uptake ≤50% of those who are eligible and express an interest (Red), 51%-74% (Amber), ≥75% (Green) (ii) intervention fidelity – % of intervention arm participants who have at least one contact with a VSW <40% (Red), 40-65% (Amber), >65% (Green) (iii) primary outcome data at 6 weeks follow-up <60% (Red), 60-80% (Amber), >80% (Green)
Main trial	To investigate the effectiveness of adding a brief vocational support intervention to usual primary care in reducing the number of days absent from work over 6 months in patients who receive a fit note when consulting at their general practice.	Number of days absent from work over 6 months.
Linked qualitative interviews	To understand how the perspectives and experiences of patients, VSWs, healthcare professionals (HCPs), and employers/line-managers influence their decision-making around work absence and RTW, experiences of receiving and delivering the vocational support intervention and its delivery in practice.	Perspectives and experiences of participants, VSWs, HCPs, and employers/line-managers on work absence, the influences on each groups' decision-making around absence and RTW; the VSWs experiences of delivering the intervention and its delivery in practice; participants' experiences of the receipt of the vocational support and whether/how it supported RTW, and participants' decision-making in deciding to RTW.

iv) Feasibility study flowchart



v) Internal pilot and main trial flow chart



1. Background

The availability of vocational advice in the UK is highly variable [Black 2008], and is often accessible only to those working for larger organisations. In 2017 there were 5.7 million small and medium sized enterprises (SMEs) in the UK (businesses with fewer than 250 employees) which was over 99% of all businesses.[House of Commons Library 2017] Total employment in SMEs was 16.1 million accounting for approximately 60% of all employees.[Federation of Small Businesses 2018] It is estimated that only 31% of all employees have access to occupational health[Fit for Work Europe 2018] and the quality of these services in supporting return to work (RTW) is variable, leaving many employees at risk of not being able to access appropriate advice and support early in their absence. Fitness for work is a key strategy in UK Government policy, and with the recent establishment of the Health and Work Unit bringing together the Department for Health and Social Care with the Department for Work and Pensions, the Government has demonstrated a sustained policy interest in this field.[Back 2008, Fit for Work Europe 2018, DWP and DoH Improving Lives 2016] There have been previous attempts to offer greater support for RTW, for example Access to Work[DWP Access to Work 2018] and The Work Program,[DWP The Work Program] of which perhaps the most notable was the Fit for Work Service, initiated in 2015 and offered throughout the UK albeit with variable access. Through this service, clients were able to access support by phone or online "chat" for free, expert, impartial advice about managing their health at work. However the service was decommissioned in 2018 due to a lack of awareness of the service and consequent low uptake.[GP Online 2018] The recent closure of the Fit for Work advice phone line means that there are fewer opportunities for patients and GPs to access vocational advice and support.[Personnel Today 2018] Consequently many patients are certified absent from work without vocational advice to help them back into the workplace, potentially extending work absence and exacerbating the negative consequences of this.[Waddell *et al* 2016, Claussen *et al 1993*]

In primary care, the responsibility to manage the impact of health on work largely falls to general practitioners (GP) through the fit note. The fit note was introduced in 2010 and allows the GP to decide whether a patient is not fit for work, or may be fit for some work taking into account advice (such as phased return to work; altered hours; amended duties; workplace adaptations), with free text space for details. Patients can self-certify sickness absence for up to seven days, after which point a fit note is required to access statutory sick pay [ref to Government website https://www.gov.uk/statutory-sick-pay]. The number of days lost from work in 2016 was estimated at 137.3 million days,[Office for National Statistics 2014] and approximately £13 billion is spent on health-related sickness benefits per year,[Office for

National Statistics 2014] the key drivers of these costs are mental health (MH) and musculoskeletal (MSK) disorders.[Linaker *et al* 2011] Importantly, 30% of GP consultations for MH conditions and 35% for MSK conditions result in certified work absence.[Wynne-Jones *et al* 2009] But most GPs lack confidence in providing vocational advice, defined here as the provision of advice and guidance directed towards supporting a patient's return to work. GPs report difficulties with completing the fit note, may feel it conflicts with their role as patient advocate, and many do not feel that vocational advice is part of their role. [Hiscock *et al* 2001, Engblom *et* al 2011] This leads to longer-term absences and associated poor work and health outcomes including persistent MH and MSK conditions and increased risk of work disability, defined as temporarily or permanently leaving the labour market or having a reduced capacity to work.[Waddell *et al* 2006, Claussen *et al* 1993, van Vilsteren *et al* 2015] Patients often have both MH and MSK conditions and there is increasing evidence that being engaged with the workplace is good for an individual's physical and mental health [Waddell *et al* 2006, Claussen *et al* 1993, Head *et* al 2008, Fit for Work 2017] and that work absence causes poorer mental and physical health, increased mortality and indebtedness.[Nordstrom *et al* 2014, DWP Understanding Journeys from Work 2015] Of new claimants of Employment and Support Allowance, 61% had sickness absence from their last job, 75% of whom decided to stop working themselves.[DWP Understanding Journeys from Work 2015] With better vocational advice and support early on, in primary care, this choice may have been different.[Lambeek *et al* 2010, Linton *et al* 2016] Improving the provision of vocational support in primary care may improve patients' health, quality of life and benefit society from active engagement in the workforce.[Marmot 2010] Whilst GPs have a key role in advising and supporting patients back into work,[Claussen *et al* 1993] the role of other health professionals and non-health professionals in managing this interface is advocated,[Waddell *et al* 2008, NICE 2009] with recent legislation allowing physiotherapists, psychiatrists and senior nurses to assess fitness for work.[Chartered Society of Physiotherapists 2018].

There is a paucity of research into vocational support and previous studies have the following limitations: i) most focus on the workplace only and not the interface between health and work [van Vilteren *et al* 2015]; ii) many focus on specific health conditions, such as MSK pain [Wynne-Jones *et al* 2018, Drake *et al* 2016]; iii) few take a UK healthcare perspective. The inclusion of early work-directed interventions, including all stakeholders, has been demonstrated to be effective and cost-effective in depression and MSK pain.[Nieuwenhuijsen *et al* 2014, Carroll *et al* 2010] Models of integrated health and occupational support have been tested in other countries (Sweden and the Netherlands), leading to fewer days work absence, earlier RTW and reductions in healthcare use.[Linton *et al* 2016, Lambeek *et al* 2010] There

are a small number of UK studies that have tested interventions to manage work absence in those with health conditions, and these have informed the WAVE trial.[Wynne-Jones *et al* 2018, Hillage *et al* 2015, Rannard *et al* 2014] The Fit for Work Service pilots tested different models of delivering vocational support but only 21% of referrals came from general practice. [Hillage *et al* 2015] A recent UK RCT aimed to provide vocational support in primary care but lack of GP engagement led to poor recruitment and therefore an inability to robustly test the intervention.[Rannard *et al* 2014] A successful UK study, our Study of Work And Pain trial (SWAP trial; n=338 patients from 6 GP practices), demonstrated the effectiveness of adding a brief, early, vocational support intervention to best primary care alone (primary outcome of work absence over 4 months: 9 days versus 14 days; return on investment: £49 for every £1 spent).[Wynne-Jones *et al* 2018] Learning from the SWAP trial and linked interviews with patients, vocational advisors and GPs suggested that those with at least two weeks of work absence benefited more from the intervention than those with shorter periods of work absence, a finding supported by other research.[van Dujin *et al* 2010, Demou *et al* 2016, Vargas-Prada *et al* 2016] The SWAP trial offered the vocational advice intervention to patients consulting with MSK pain, and it is not known whether and how the intervention might be amended for use with a broader range of primary care patients, particularly those with common MH conditions. Parallels can be drawn between RTW processes in MSK pain and MH, and the following interventions have been shown to be effective for both types of condition: case management [Durand *et al* 2014]; provision of work accommodations [Waddell *et al* 2008]; addressing obstacles to work that are clinical, psychosocial and organisational (akin to the Flags model) [NICE 2009]; stepped care [van Straten *et al* 2015]; programmes tailored to individual patients [Martin *et al* 2012]; and telephone-based intervention [Rollman *et al* 2016]. Our SWAP trial intervention for adults with MSK pain included these evidence-based interventions.[Wynne-Jones *et al* 2018] The SWAP trial also underlines the business case for the provision of early vocational advice. We estimated using SWAP trial data that at a threshold of £20,000/Quality Adjusted Life Year (QALY) gained, the new intervention investigated in this new trial (WAVE) would need to result in at least 0.0024 additional QALYs to be cost effective. Using the 95% confidence intervals around the mean cost difference (-£209.58 to £305.68), at the higher value, the QALY difference would need to be at least 0.015.[Wynne-Jones *et al* 2018] By way of a conservative estimate, if the WAVE trial shows that the vocational support intervention reduces the days lost from work by a modest degree of 5 days (for example, 9 days versus 14 days in the control arm (data from the SWAP trial)), this could lead to cost savings of up to £2.5bn to the UK economy and ensure that the health and broader social and economic benefits of being in work to the individuals involved are realised.

Offering vocational support early, in primary care, where most patients with health conditions resulting in time off work are consulting, is a key potential solution to the current lack of universal provision of vocational support. We have previously shown the benefits of this type of intervention for adults with MSK pain.[Wynne-Jones *et al* 2018] The WAVE trial will test whether our previously developed vocational advice intervention can be adapted for, delivered to, and be effective with, a much broader group of patients consulting in primary care whose health condition is impacting on their ability to work. The trial will be in the context of recovery from the COVID-19 pandemic.

2. Aims and objectives

The overall aims of the WAVE trial are to determine, in patients consulting in general practice who receive a fit note, whether the addition of a brief vocational support intervention to usual primary care leads to fewer days lost from work, and whether offering this vocational support is cost-effective.

2.1. Objectives

In order to meet the above aims, a feasibility phase will be undertaken followed by a RCT with internal pilot. Participants will be randomised to usual primary care or usual primary care plus a brief vocational support intervention, with follow-up using SMS text messaging to record work absence in the short-term and postal questionnaires to record longer-term outcomes.

Specific objectives are split into those related to the feasibility phase and those related to the internal pilot and RCT phase as follows:

2.1.1. Feasibility phase objectives

(i) Convene an expert advisory group including lay people (with MH and other conditions), academics, health psychologists, occupational health physicians and nurses, occupational therapists and relevant others with experience of managing health and work to achieve consensus on refining the content of the intervention, and identifying potential mediators of the intervention to be tested in the main trial.

(ii) Explore with Patient and Public Involvement and Engagement (PPIE) members (including those working with health conditions and employers) the acceptability of the vocational support intervention developed and tested in the SWAP trial, for use with patients with MH and other health conditions, and where needed adapt the intervention to meet their needs.

(iii) Develop and deliver a training package and a manual to support VSWs to deliver the work-focussed vocational support intervention, taking account of the needs of patients including those with comorbid physical and MH conditions.

(iv) Test the patient identification methods, approach to screening for eligibility and patients' willingness to engage with the vocational support intervention and test the fidelity of intervention delivery, in a single group feasibility study with 30 participants.

For the linked qualitative interviews:
(v) Understand patient participants' experiences of being invited to participate, the delivery of the vocational support intervention and the usefulness of the intervention in supporting them to RTW.

2.1.2. RCT primary objective

Investigate the effectiveness of adding a brief vocational support intervention to usual primary care in reducing the number of days absent from work over a period of 6 months in patients who receive a fit note when consulting at their general practice.

2.1.3. RCT secondary objectives

(i) Determine the cost-effectiveness of offering the vocational support intervention in addition to usual primary care.

(ii) Investigate time to RTW and compare this between trial arms.

(iii) Investigate factors mediating observed differences in outcomes between the trial arms (e.g. RTW self-efficacy, health symptoms and fear avoidance beliefs).

For the linked qualitative interviews:
(iv) Understand how the perspectives and experiences of trial participants, VSWs, HCPs, and employers/line-managers influence their decision-making around work absence. Understand participants' experiences of receiving, and the acceptability of, the vocational support intervention and its delivery in practice.

3. Adaptation of the vocational support intervention

3.1. Study design

An 18-month feasibility phase focused on adapting and manualising the vocational support intervention used previously in the SWAP trial [Wynne-Jones *et al* 2018] to broaden its scope for use with patients with a broad range of health conditions, and a process evaluation testing recruitment methods, patients' willingness to engage with the intervention and intervention fidelity, including linked qualitative interviews with participants.

3.2. Convene an expert advisory group

An expert advisory group will be convened to guide the adaptation of the vocational support intervention. The group will consist of experts working in the field of health and work and the following groups will be invited to participate: academics working in vocational rehabilitation research; health and occupational psychologists; occupational physicians and nurses; occupational therapists; relevant others with experience of managing health and work and employers or their representatives (e.g. human resources). We will ensure we have a group with experience of the broad range of health conditions which result in fit notes in primary care including MH, MSK, other physical conditions and multi-morbidities. This expert advisory group will bring complementary knowledge and skills to guide the adaptation and refinement of the intervention for the WAVE trial. The expert group will also contribute to refining the draft logic model for the intervention that will detail the anticipated mediators or mechanisms through which the intervention is anticipated to work.

3.3. Convene a PPIE group

A patient and public involvement and engagement (PPIE) group will be established to include the WAVE trial PPIE co-applicant and participants who have health conditions (including MH, MSK, other physical health conditions and multi-morbidities) and who have experienced both short- and long-term work absence as a consequence of these conditions. The PPIE group will review the components of the intervention developed for the SWAP trial to assess its usefulness for a broader range of patients. The PPIE group will use their unique experiences to assist in recommending adaptations to the intervention to meet the needs of the broader population to be included in the WAVE trial.

3.4. Adaptation of the vocational support intervention

The vocational support intervention will be based on that successfully used in our previous SWAP trial. [Wynne-Jones *et al* 2018] The SWAP trial intervention was developed for, and tested with, patients consulting in primary care with MSK pain so it is important to adapt this

intervention to ensure that it is relevant to a broader range of patients with different health conditions. The processes of this adaptation are detailed below.

3.4.1. Design and theoretical/conceptual framework of the vocational support intervention

The WAVE trial intervention builds on that developed for the SWAP trial, which utilised the Flags model and stepped care.[Wynne-Jones *et al* 2018] The Flags model is designed to identify obstacles to work in three distinct categories (i) Yellow flags or psychological obstacles to recovery e.g. perceptions, beliefs and behaviours including self-efficacy to return to work (ii) blue flags or work related social factors e.g. perceptions of the workplace/supervisors/colleagues, low social support, and (iii) black flags which are the compensation or system barriers to recovery e.g. workplace and national work absence policies, financial strain.[Kendall *et al* 2009] The SWAP trial intervention involved identifying obstacles to work, problem solving these with a vocational advisor, developing and agreeing a RTW plan and date, followed up with review of progress. The SWAP trial found that, of the secondary outcomes measured, RTW self-efficacy, productivity and presenteeism were impacted by the intervention. Self-efficacy is included as a key component in several psychological behaviour change models (e.g. Social Cognitive Theory, Protection Motivation Theory, Health Action Process Approach) and high levels of self-efficacy have consistently been associated with positive behaviour change.[Sheeran *et al* 2016] However, the WAVE intervention is anticipated to address additional cognitions, beliefs, emotions and behaviours that are also obstacles to RTW. Current thinking in the behaviour change field suggests that intervention development should draw on multiple theories.[Schaalma *et al* 2009] Michie *et al* [Michie *et al* 2009, Michie *et al* 2016] have brought together behaviour change theories so that researchers can draw from a range of theoretical models and behaviour change techniques, rather than focusing on one only, which may not include all the elements that are thought to be important. In the feasibility phase of WAVE, the intervention previously developed and tested in the SWAP trial will be refined with the help of stakeholders to ensure that the intervention is acceptable to those with other health conditions. The initial logic model (Figure 1: Vocational Support Intervention Logic Model) shows how we envisage the WAVE trial intervention in terms of its components, key treatment targets and key mediating factors, and the anticipated behaviour change techniques that we expect the VSWs will utilise.

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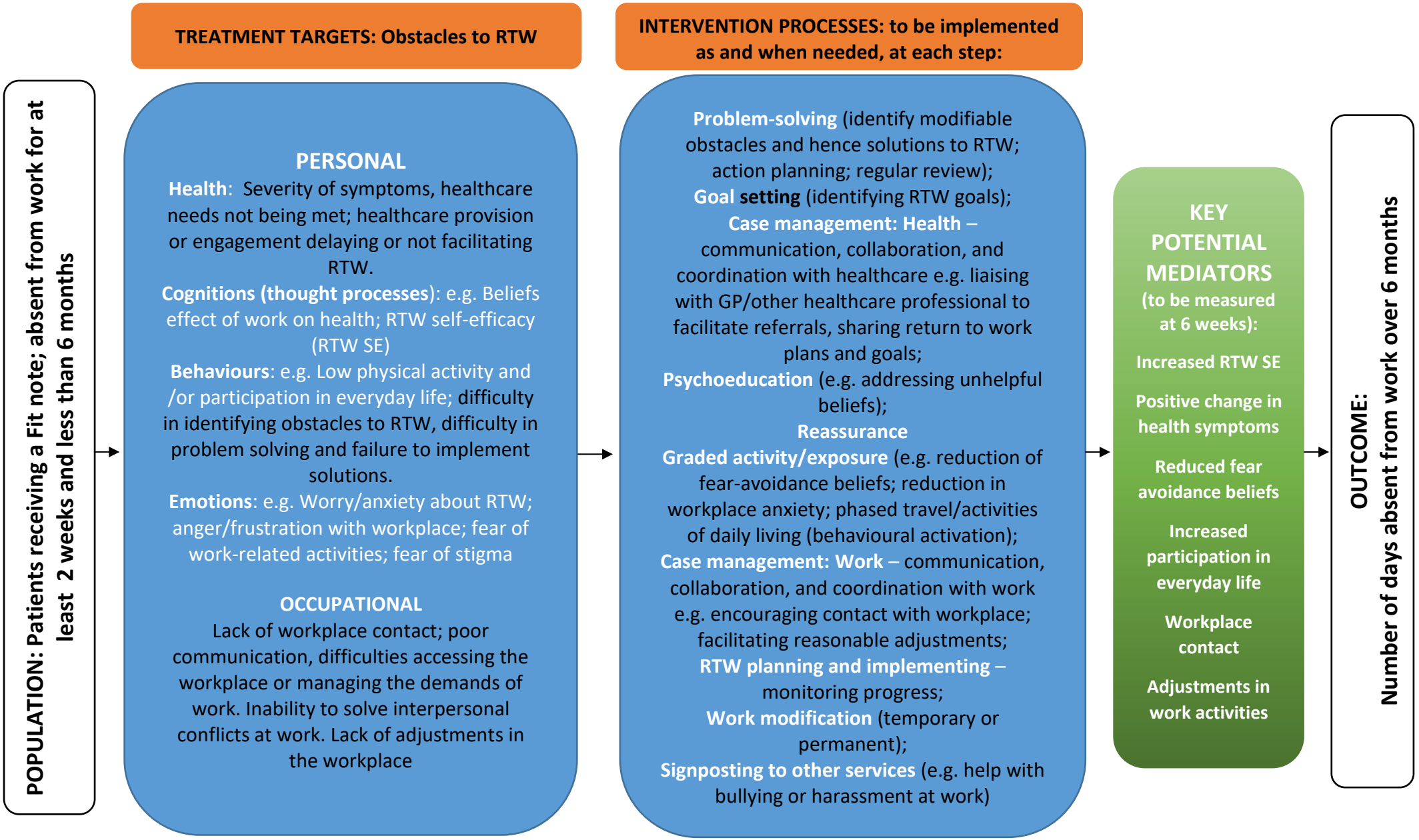
Figure 1: Vocational Support Intervention Logic Model (initial version)



3.4.2. Content of vocational support intervention

The intervention will be manualised to facilitate the use of the content and resources by the VSWs throughout the trial and to ensure that there is an output that may be utilised in implementation of the intervention subsequent to the trial. The intervention will elicit and address participants' modifiable health, cognitive, emotional, behavioural, work and wider socioeconomic obstacles to RTW in order to achieve an early, safe and sustained RTW. The intervention's initial logic model (Figure 1: Vocational Support Intervention Logic Model) summarises the anticipated content of the intervention, although this is likely to be modified depending on the results of this feasibility phase. Guided by the obstacles identified to RTW, the intervention will seek to address the following:

<u>Personal</u>

Health: Severity of symptoms, healthcare needs not being met; healthcare provision or engagement delaying or not facilitating RTW.

Cognitions (thought processes): e.g. unhelpful attitudes and beliefs about health and/or work and/or working with symptoms associated with health conditions, RTW self-efficacy.

Behaviours: low levels of physical activity and/or participation in everyday life, failure to identify obstacles to RTW, failure to problem solve and implement solutions, lack of effective contact with the workplace.

Emotions: worry or anxiety about RTW; anger/frustrations with workplace.

<u>Occupational</u>

Lack of workplace contact; poor communication, difficulties accessing the workplace or managing the demands of work. Inability to solve interpersonal conflicts at work. Lack of adjustments in the workplace.

In order to address these potential obstacles (and others identified by the VSW and participant), a range of techniques will be utilised by the VSWs. These are expected to include: goal setting, facilitation of problem solving, guided discovery, information provision, facilitation of graded activity and exposure, collaborative action planning, communication, collaboration and co-ordination with stakeholders (including GPs, other healthcare providers, employer and other stakeholders), facilitation of temporary or permanent adjustments to work, collaborative RTW planning and implementation, progress monitoring, and signposting to additional services and resources (e.g. information and support with workplace problems such as bullying and harassment,

interpersonal conflict or wider socio-economic factors such as housing or debt, local services and support groups for specific health conditions, other healthcare services).

3.5. Delivery of vocational support intervention

3.5.1. Who will deliver the intervention?

Careful thought has been given as to who should be in the role of VSW and deliver the intervention. The skills required to successfully support RTW include: professional credibility, communication skills, evaluation, evidence gathering, conflict resolution, and problem-solving.[Pransky *et al* 2010] It is necessary to ensure a balance in focus between health and work, and staff undertaking a role need to have the skills, focus and attitudes necessary to deliver effective vocational support.[Waddell *et al* 2008] The previous SWAP trial reported the clinical knowledge required for a VSW should include understanding the likely impact on work participation rather than detailed understanding of the clinical course or management of the specific health condition(s).[Sanders *et al* 2017] Learning from SWAP and other research [Pransky *et al* 2010] we propose a skills-based role description drawing VSWs from professions including physiotherapy, psychology, nursing, occupational therapy and IAPT (Improving Access to Psychological Therapies) practitioners, as well as non-health professionals with experience of facilitating return to work (such as occupational health assistants or employment advisors). We will describe the characteristics of the VSWs in the WAVE trial and include modelling of different providers of the intervention in the health economic analysis.

3.5.2. How will the intervention be delivered?

As the vocational support intervention comprises a stepped model of care, participants will only receive the level of support that they require to achieve ***sustained RTW defined as return to any work for at least 4 weeks***, this would include those who RTW in their previous occupation with adjustments and those who return to temporary, alternative work.[Young *et al* 2016] The level of intervention and the number of contacts with the VSW will be tailored to the needs of each participant. All participants will be offered Step 1, and the decision on whether the participant needs to step up to the next level will be based on discussion between the participant and the VSW.

Step 1: An initial telephone consultation to discuss the impact of their health condition on their work. Evidence based information, reassurance and support relating to the individual's health condition will help address common myths about the relationship between health and work and around working with health conditions and/or symptoms. The VSWs will then begin to help the

participant identify what their obstacles to RTW are and enable the participant to find solutions to modifiable obstacles. This will result in the participant developing a RTW plan which addresses the identified obstacles and the next steps the participant needs to take to facilitate their RTW, with the aim of setting a RTW date and arranging a follow-up contact with the VSW. At follow-up, participants who have not achieved RTW will be invited to explore the obstacles that have prevented this, and the VSW will help them clarify the steps that the participants can take to address any current or new obstacles and a revision of the agreed RTW plan. The VSW will also act as the case manager and facilitate communications between the participant and their healthcare team and workplace as required, and only with the permission of the participant.

Step 2: Participants will be invited to a face-to-face meeting, either in person or via videoconferencing, depending on participant preference. The VSW will spend more time working with the participant helping them to identify and overcome obstacles to return to work. It is anticipated that face-to-face / video consultations will last up to one hour and be offered in a range of venues including but not limited to healthcare or community settings.[Wynne-Jones *et al* 2018] The VSW will support the participant in developing an updated RTW plan and agree a follow-up contact date to assess RTW status. Additional information, advice and support will be provided if needed through case management and signposting to other services. A follow-up contact with the VSW will be arranged and at follow-up, participants who have not achieved RTW after face-to-face consultations will be offered Step 3.

Step 3: This step is focussed not only on providing participants with practical strategies to support their RTW but also involves the VSW contacting the participant's workplace (with consent). It is anticipated that contact with the workplace will involve a discussion based on the RTW plan and potential adjustments to support RTW, between the participant, their employer (or supervisor/line manager) and the VSW either by email, phone, video conference or in person.

3.5.3. Completion of the vocational support intervention

Throughout the intervention the VSW and the participant will be working towards a planned completion of the vocational support intervention. Participants can complete the intervention in one of two ways; by achieving sustained RTW or remaining absent from work for 6 months or more. Sustained RTW is most commonly defined as return to *any work* for at least 4 weeks,[Young *et al* 2016, van Egmond *et al* 2015, Viikari-Juntura *et al* 2012] and this is the definition we will use in the WAVE trial, therefore participants who RTW with adjustments (including temporary

alternative work or different hours of work) will be deemed to have a successful outcome. Once participants have returned to work they will be able to contact the VSW throughout the following 4-week period to access further support or information if required. Where participants have not achieved sustained RTW by 6 months, they will be directed by the VSW towards state level support to manage their health and work and as such they will be signposted to the Jobcentre Plus for advice and if appropriate, on starting an application for Universal Credit. The delivery of the vocational support intervention will be supported by an intervention manual including standardised Case Report Forms (CRFs) to ensure that there is consistent documentation of the intervention delivered. The CRFs' content will allow intervention fidelity to be assessed. The CRFs will also act as a record for the VSW to ensure continuity in follow-up consultation(s) and to document the obstacles identified and what was done to overcome these. The CRFs will also serve as a record of the "dose" of vocational intervention delivered by allowing the research team to calculate the proportion of participants offered and accessing each step of the intervention. We anticipate many participants will only access Step 1 (approximately 60% is conservatively estimated; based on the results from the SWAP trial where 80% accessed Step 1 only, with fewer accessing Steps 2 (approximately 30%) and 3 (approximately 10%). Importantly, in the SWAP trial, participants who had no absence from work were eligible to take part, whereas in WAVE only those with at least two weeks of absence will be included

3.6. VSW training programme

Utilising the expertise of the expert advisory and PPIE groups and the learning from the SWAP trial [Wynne-Jones et al 2018] and the wider literature, the training package used for the vocational advisors in the SWAP trial will be adapted to address the needs of the broader patient population in the WAVE trial (MH, MSK, other physical conditions and multi-morbidities). This training package will take into account the professional background(s) of the VSWs (anticipated to be varied) and their learning needs. The adapted training package will guide the development of an intervention manual designed to support the VSWs in delivering the intervention in the WAVE trial.

The VSW training program will consist of the following: i) a short face-to-face, video-conference or online course (depending on COVID-19 restrictions) aimed at equipping the VSWs with the knowledge and skills to deliver the intervention ii) evaluation iii) supervision.

vi) Face to face / videoconference / online training

Training will be developed to support the VSWs to deliver the intervention. A variety of methods will be used to deliver this, for example, PowerPoint presentations, role-play, and case studies. The training programme will include the provision of examples of participants who might be seen as part of the WAVE trial. These will be based on real life (anonymised) participants and the experience of the research team, ensuring that the VSWs gain experience in managing the types of participants likely to participate in the trial. The training is also intended to draw upon VSWs own experiences. Discussion will help the VSW understand how to implement vocational support for these cases. The VSWs will also be provided with resources throughout their training designed to support their consultations, with ongoing access to these resources. The training will be led by members of the WAVE research team with experts identified from the advisory groups providing additional specialist advice if necessary. The core team developing and delivering the training will be led by co-applicant Sowden (consultant physiotherapist with expertise in designing and delivering training for complex interventions, including vocational advice), and include additional co-applicants as described in Appendix 2. The topics covered in the training will include those relating to the delivery of the intervention as well as those relating to identifying and addressing obstacles to RTW (linked to the factors believed to mediate the relationship between health and work): At the end of the course the ability of the individual VSWs to apply the knowledge acquired from the course to at least one case study will be assessed. The purpose of this is to identify individual VSWs areas of strength and weakness, reinforce what they are doing well and provide constructive feedback and support to help them address any areas of weakness.

Topics in the training programme	
Background and context ▪ Stepped care ▪ Case management ▪ UK Sickness absence policy and practice; health and employment legalities ▪ Relationship between health and work ▪ Value of work ▪ Obstacles to RTW ▪ Roles and responsibilities of key stakeholders ▪ What works in vocational rehabilitation ▪ Impact of COVID-19 restrictions **Eliciting and assessing health, personal and occupational obstacles to RTW** ▪ Communication skills	**Assessing health, personal and occupational obstacles to RTW** ▪ Problem solving and case management of obstacles to RTW ▪ Collaborative goal setting; agreeing action plans ▪ Addressing non-evidence based/work incompatible cognitions, behaviours and emotions (e.g. psychoeducation, behavioural activation). ▪ Facilitating timely, appropriate and work focussed access to health care ▪ Encouraging contact with the workplace, VSW liaising with the workplace, ▪ Developing, implementing and monitoring RTW plans

▪ Telephone and face to face / video consultation skills ▪ Questions to explore health and work situation and facilitate disclosure of obstacles ▪ Responding to disclosure of risk (e.g. red flags or suicidal ideation or intent)	▪ Facilitating work modifications, reasonable adjustments, resolving difficulties accessing the workplace ▪ Developing, implementing and monitoring RTW plans ▪ Signposting

vii) Evaluation of the training

All VSWs will complete a pre-and post-training questionnaire to assess their knowledge, self-reported behaviour and confidence in delivering the vocational support work intervention. The questionnaire will be paper or video case vignettes. In addition, the VSWs will complete a training experience questionnaire post training in order to gain their feedback on the training content, structure, dose and methods of delivery.

viii) Supervision

Throughout the feasibility phase and randomised trial, group supervision provided by the training team will take place, either face-to-face or via videoconferencing (anticipated to be no more than 1.5 hours per month). Supervision will ensure that all VSWs have access to a professional experienced in delivering vocational support, ensuring that they can ask questions about specific cases. The supervision will also provide the VSWs with peer and mentoring support. Discussion between the supervisors and VSWs will consolidate and further develop their knowledge and skills, support the VSWs to put the training into practice with participants, resolve practical issues that might arise and support fidelity in delivery of the intervention. Supervision has been used successfully in trials of complex interventions, for example in our previous SWAP and STarT Back trials both of which included interventions targeting work outcomes.[Wynne-Jones *et al* 2018, Hill *et al* 2011]

4. Single arm feasibility study

A single group feasibility study will be undertaken in three centres [Keele (West Midlands), London and Southampton n=30 (aiming for 10 participants from each centre)]. The purpose of this feasibility study is to test the two methods of participant identification from 'real time' primary care consultations and from review of primary care electronic medical records that are tagged when a fit note is issued. We will also examine participants' willingness to engage in research about vocational support, examine the numbers and proportions who are eligible, who consent to participate in this study, and who engage with the intervention, the level of intervention delivered

(i.e. steps reached including number and duration of phone calls, face to face / video consultations and workplace contacts) and intervention fidelity. Assessment of fidelity will be based on examining the content of the consultations participants have with the VSWs, achieved in two ways: (i) recording phone calls and face to face / video consultations between the VSWs and the participant (with participant consent); (ii) examining Case Report Forms (CRFs) completed by the VSWs detailing whether intervention was offered and the content of the intervention received. A checklist of the expected content of these consultations will be developed and used by the research team to assess intervention fidelity, based on the contents of the training package and VSW manual. To supplement the use of the checklist, up to ~10 of the recorded phone calls and face to face/ video consultations between VSWs and patients will be transcribed and subjected to more detailed qualitative analysis, using targeted conversation analysis techniques (Sidnell and Stivers, 2015) for rapid investigation of *how* the different intervention components are delivered.

Lastly, we will test the follow-up methods, which include SMS text messaging for up to 6 weeks and a questionnaire at 6 weeks follow-up (from enrolment).

4.1. Regulatory approvals

Prior to the start of recruitment, we will obtain approval from the study Sponsor before seeking Health Research Authority (HRA) Approval, which is the process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent NHS Research Ethics Committee (REC) opinion provided through the UK research ethics service. Approval from the study Sponsor followed by the HRA will also be sought in relation to all study amendments.

4.2. Inclusion/Exclusion Criteria

Eligibility criteria have been informed by subgroup analyses of the previous SWAP trial data [Wynne-Jones *et al* 2018] which suggested that the vocational advice intervention was more effective in those participants who had at least two weeks absence from work. This is also supported by other literature.[van Dujin *et al* 2010]

Inclusion criteria:

1) adults aged 18 years and over
2) currently in paid employment (full or part time)
3) current absence from work of at least two consecutive weeks but not more than six continuous months

4) received a fit note
5) access to a mobile phone that can receive and respond to SMS text messages
6) able to read and write English
7) able to give full informed consent
8) willing to participate.

Exclusion criteria:

1) long-term work absence defined as over six continuous months
2) pregnancy or on maternity leave
3) patients presenting with signs or symptoms indicative of serious illness requiring urgent medical attention ('red' flags)
4) severe mental health problems (e.g. severe depression with risk of self-harm, exacerbation of schizophrenia or bipolar disorder, cognitive impairment or lack of capacity)high vulnerability (e.g. palliative stages of illness, recent bereavement, dementia).

All patient-facing material will be in English and therefore it will not be possible to include patients who are unable to complete written questionnaires / SMS messages in English. The participant information sheets and questionnaires will include the contact number of Keele CTU which patients can call to discuss any difficulties with completion of the consent form, questionnaire or SMS messages.

4.3. Identification of potential participants

In order to maximise participant recruitment to the WAVE trial whilst minimising burden on general practices and their staff, identification of potential participants will be as automated as possible. Potential participants will be identified when they consult at one of the participating practices and receive a fit note for time off work. To ensure that a consecutive sample of potential participants are identified, a health informatics specialist from Keele CTU will develop the computer system processes to identify potentially eligible participants. General practices will be able to use one of two methods described below, both of which have been successful in our previous trials.[Foster *et al* 2017]

4.3.1. Identification through an automated health informatics IT protocol during 'real-time' consultation (Method A)

Identification of potentially eligible patients through the use of an automated medical record protocol (a "pop-up") activated when a clinician completes an electronic fit note (eMED3) in the electronic medical record, which is automatically coded with a clinical code by the EMIS or

SystmOne medical record system. The pop-up will only trigger if the patient is 18 or over, and there are no clinical codes in the patients' medical record that match the exclusion criteria (detailed in section 4.2). The pop-up will serve several purposes: to flag potentially eligible participants to the consulting clinician; to prompt the clinician to check the patients' eligibility for the study by reviewing the list of eligibility criteria (confirmation of eligibility will be automated where possible so that the pop-up does not fire for those patients who clearly do not meet the eligibility criteria); to prompt the clinician to mention the research study to potentially eligible participants and to ask the patient if they are willing to receive further information about the study and give their consent to share their contact details with the research team. The pop-up will automatically record, using clinical codes, patients' eligibility and consent for further contact. This health informatics IT protocol ensures that the research team will subsequently know how many times the pop-up was fired in each practice.

4.3.2. Identification through back dated searches of the general practice medical record after the consultation (Method B)

Since consultation styles vary in general practice, it is possible that some eligible participants will be missed using the previously described identification approach, as the clinician may not code the fit note in the electronic medical record until after the patient has left the consultation room, or the clinician may have no time to discuss the study and gain consent for further contact. Therefore, a second identification method will be tested. For those clinicians who code following the consultation, a modified pop-up will activate upon entry of the fit note code. The modified pop-up will include everything except patient consent to share contact details with Keele CTU, the clinician will still have to screen the patient for eligibility as in the first method. Tagged records will be downloaded at the end of the week by general practice staff, who will then send a study pack, with a letter of invitation on Practice headed paper.

Clinical codes for fit notes

General practice IT clinical systems all use a clinical coding system for the recording of patient findings and procedures. Since 2018, all general practice IT systems have begun a process to migrate to using a single terminology, SNOMED CT, across England. SNOMED CT is a multinational and multilingual terminology, with country specific editions available which augment the international edition and can cross map to other terminologies such as Internal Classification of Diseases (ICD) 10. Read codes were originally created to record the eMED3 (fit note) and can be mapped to the eMED3 codes created in the SNOMED CT UK edition. For both

identification methods described above, the list of relevant Read / SNOMED Codes will be compiled based on previously developed and tested code lists for fit notes and for the study's inclusion and exclusion criteria.

Where a participating practice uses the EMIS Web clinical system, we will utilise a system data variable, Anonymised Identifier. This pseudonymised identifier is a hashed variable, which is generated by an EMIS algorithm which maps the original string of identifiers to data of a fixed length protecting the security of the original data. This unique identifier is linked to a single patient whilst they are registered at an individual practice and only the general practice staff who have the appropriate access rights to search, report and view patient identifiable data can decrypt this system identifier. The Anonymised Identifier will be included, with date of birth and gender in all data export reports provided to the research team to facilitate the analysis of pseudonymised datasets for the purposes stated in this protocol. By utilising the EMIS system generated code, patient's identifiable data are retained by their general practice until patients consent to participate in the research study when following recruitment Method B.

4.3.3. Identification and recruitment of general practices

National Institute for Health Research (NIHR) West Midlands, South London and Wessex Clinical Research Networks (CRN) will identify general practices. A feasibility assessment will be conducted as part of the site identification process to ensure a sufficient number of patients that have been issued a fit note are registered at that practice and that the practice identified can meet the study requirements to deliver the study on time and on target. Only those practices that meet the site feasibility requirements will be selected to participate.

4.4. Invitation and recruitment

After receiving the study pack, all patients will have time to consider their participation in the study and discuss with friends and family in their own time, the study pack will also have a contact telephone number for Keele CTU who will be able to answer further questions if required.

The study pack will include:

- Invitation letter
- Participant information sheet (PIS)
- Baseline questionnaire with consent form and elgibility question at the front to check if they are still absent from work

- Pre-paid reply envelope

The invitation letter will introduce the study to the patient and explain how they were selected for invitation to the study.

The PIS will summarise the study and tell the patient what is involved should they wish to participate. The contact details of Keele CTU will be provided should potential participants have any further questions about the study or have any difficulty in completing the consent form or baseline questionnaire.

Prior to completion of the consent form, the participant will be instructed to answer one eligibility question relating to whether they are still absent from work (Yes / No).

- Are you still absent from work as a result of your health condition?

Participants who respond 'No' to this question will be advised not to complete the remainder of the questionnaire. Participants will be informed that the study is not suitable for them, thanked for their time and asked to return their questionnaire to Keele CTU using the pre-paid reply envelope provided. Only participants who respond 'Yes' to this question will be eligible to take part in the study, will be asked to complete the remainder of the questionnaire and, following consent, will be considered 'study participants'.

Participants who answer "Yes" to this question will be asked to complete, sign and date a consent form confirming that: they have read and understood the PIS and are willing to take part in the study; understand that a questionnaire will be sent at 6 weeks; consent to receive a fortnightly SMS text message to collect data on RTW for up to 6 weeks (up to 6 months in the main RCT see section 4.5.9); may be invited to participate in an interview; understand that their GP will be notified about their participation in the study, and that they are aware they can withdraw at any time without giving a reason and if they do withdraw that their clinical care will not be affected.

Participants will additionally be asked to consent to a pseudoanonymised electronic copy of relevant sections of their general practice medical records being extracted to allow authorised members of the research team to review information relevant to the study.

The returned consent form will be checked to ensure that it is complete. Recruitment to this feasibility phase will be complete when the returned questionnaire confirms the patient is still eligible, they have signed and dated their consent form (recruitment to the main RCT phase will also include randomisation see section 7.2) and completed key the primary outcome data. Any

missing data in the completion of the consent form, eligibility question or primary outcome data, will be followed up by post, telephone or email from Keele CTU.

4.5. Data collection

To collect baseline and outcome data, participants will be sent postal questionnaires shortly after the consultation during which they receive a fit note, and at 6 weeks (and 6 months for the main RCT phase). The baseline questionnaire will include the primary and secondary outcomes, key anticipated mediators, health economic variables and demographic information. The questionnaire at 6 weeks (feasibility phase and RCT phase) will include the primary outcome and key anticipated mediator variables only. The questionnaire at 6 months (RCT phase only) will be slightly longer and include the primary and secondary outcome measures, mediators and questions about self-reported healthcare use including any other vocational advice received through employers, the health service or any other agency. Table 1 Data collection schedule (questionnaires) provides a summary of the questionnaire measures and timing of the data collection.

4.5.1. Primary outcome measure

Work absence will be assessed by asking participants to report how much time off work they have had due to their health condition

- How much time off work during the past 6 months have you had because of your health condition? Please write the total number of days you were off work due to your health condition in the past 6 months (Days).

4.5.2. Secondary outcome measures

Participants will be asked fortnightly whether they have returned to work, for a period of 6 months or until a sustained RTW is achieved (defined as return to *any work* for at least 4 weeks). RTW will be measured via SMS text message using the following questions;

- On a scale of 0 to 10, where 0 is very poor and 10 is very good, how would you rate your general health over the past 2 weeks?
- Have you returned to work? Yes/No
- If yes, on which date did you return to work e.g. 13SEP

The full process of collecting data via SMS text message is reported in section 4.5.9.

Work interference will be measured using the Work Productivity Activity Impairment (WPAI) questionnaire [Reilly *et al* 1993]. The WPAI measures impairments to work and activities in the past seven days, it has been validated in many health conditions including MH, MSK pain,

respiratory, digestive, and cardiovascular conditions and many others [http://www.reillyassociates.net/WPAI_References5.html]. The measure has been shown to have good reliability and validity across this broad range of health conditions. The WPAI provide four types of scores; absenteeism, presenteeism, work productivity loss and activity impairment. Scores are multiplied by 100 to express percentages with higher numbers indicating greater impairment and less productivity i.e. worse outcomes.

Work performance will be measured using the Single Item Performance Question (SIPQ) as follows: On average, to what extent has your health affected your performance at work? Response options: 0 not at all to 10 My health condition is so bad I am unable to do my job. The SIPQ has demonstrated good validity and responsiveness when used in cohorts of patients seeking healthcare.[Kigozi *et al* 2014]

4.5.3. Mediators

The questionnaires will also measure anticipated key mediators that have been included within the initial logic model underpinning the intervention (Figure 1: Vocational Support Intervention Logic Model). These mediators have been selected based on published evidence indicating that they are important in the relationship between health and work, and they are modifiable through interventions. The following measures relate to the treatment targets of the logic model and include the personal (health, cognitions, behaviours) and occupational measures stated in figure 1.

Personal – health

Physical health and mental health will be measured using the Short Form 12 (SF12) [Jenkinson *et al* 1997, Ware *et al* 1996]. The SF12 measures generic health outcomes from the participants' perspective including the impact of any and all health conditions on a broad range of functional domains. The SF12 consists of a subset of 12 items from the SF36 and covers the same eight domains of health; physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health. Scoring the SF12 will provide two separate scores, the Physical Composite Scale (PCS) and the Mental Composite Scale (MCS) each score ranges from 0 to 100 where a 0 score indicates the lowest level of health and 100 indicates the highest level of health. The SF12 has been developed tested and validated by Quality Metric Incorporated [https://www.optum.com/solutions/life-sciences/answer-research/patient-insights/sf-health-surveys/sf-12v2-health-survey.html]

Depression will be measured using the Patient Health Questionnaire (PHQ) 8 [Kroenke *et al* 2001]. The PHQ 8 consists of 8 items each scored 0 to 3 providing a 0 to 24 severity score. Scores of 5, 10, 15 and 20 represent the cut points for mild, moderate, moderate severe and severe depression, respectively. The PHQ has been extensively validated, including the PHQ8 which will be used in the current study.[Kroenke *et al* 2001]

Anxiety will be measured using the Generalised Anxiety Disorder (GAD) 7 [Spitzer *et al* 2006], which includes 7 items scored 0 to 3 providing a 0 to 21 severity score. Scores of 5, 10 and 15 represent cut points for mild, moderate and severe anxiety, respectively. The GAD has also been validated for use within primary care populations.[Kroenke *et al* 2007]

Personal – cognitions

The attitudes and beliefs to work questionnaire is a newly developed measure which assesses how participants view working with health conditions. It has been used in a previous RCT [Wynne-Jones *et al* 2018]. It consists of 10 questions covering the following domains: perceptions of the nature of the health condition, financial constraints, perceptions of stressful work, legitimacy of the health condition, the sense of identity being linked to the individuals' occupation, and the impact of work absence on the individuals' wellbeing. The measure is summed (possible scores range from 0 to 60) with a higher score indicating attitudes and beliefs that may hinder return to work.

The Return To Work Self-Efficacy (RTW-SE)[Shaw *et al* 2011] questionnaire will be used to measure changes in participants' confidence to return to work. The scale consists of 19 items with each item scored from 1 to 10, scores are summed with a higher score indicating more positive self-efficacy to RTW.

Personal - Behaviours

Physical activity level (General practice physical activity questionnaire (GPPAQ3)[Department of Health], provides a 4 level physical activity index (active, moderately active, moderately inactive and inactive). The scale has been reported to be both reliable and valid (https://www.nice.org.uk/guidance/cg61/evidence/appendix-j-gppaq-pdf-196701669).

Occupational measures

Previous work absence will be assessed by asking participants whether they have experienced absence as a result of their health in the past 12 months and if so to report this absence as number of days, weeks, months. Additionally, where participants have provided consent to access their pseudoanonymised general practice medical records, analysis will be undertaken of fit notes allowing data on the number of days and number of episodes of work absence to be collected (section 4.5.6 provides more detail on the medical record extraction and review procedures).

Whilst access to vocational services is not common in the UK, participants will be asked whether they have used any other work support services (provided through health services and/or workplace based occupational health support or employee assistance programmes) and if so what advice and support these other services provided.

Additional measures relating to participants' work will also be asked including the following: current job title; what the firm/organisation they work for mainly make or do; what the participant mainly does in their job. These questions will allow participants' socioeconomic status to be calculated.[Office for National Statistics Standard Occupational Classification] The questionnaire will also ask about the participants' workplace characteristics including how many people are employed at their place of work and whether they are working full (≥35 hours per week) or part (<35 hours per week) time. Aspects of commuting have been demonstrated to be related to work absence and as such participants will be asked how much time their commute takes and how many miles their commute involves.[Kluger 1998] Participants will be asked how each of the following things about their job has been over the preceding months (dependent upon questionnaire time-point, see Table 1); support from line manager/supervisor, pace of work, feedback on performance and workload. Perceived global stress at work will be measured with the following question; "In general, how do you find your job?" with five response options: 1 = not at all stressful, 2 = mildly stressful, 3 = moderately stressful, 4 = very stressful, 5 extremely stressful.[Smith 2001] Participants' satisfaction with work will also be assessed using a single item from the Work Organisation Assessment Questionnaire. [Griffiths et al 2006]

Lastly, the questionnaire will ask participants how soon they expect to be able to resume their normal job without any limitations (within 7 days, in 8-14 days, 15-30 days, 31-60 days, not until more than 60 days, or never).

4.5.4. Health economic measures

Economic evaluation will take both a healthcare and societal perspective using a health related quality of life measure (EQ-5D-5L)[Herdman *et al* 2011] and information on primary and secondary healthcare resource use (NHS and private outpatient visits and inpatient stays), medications, out-of-pocket costs and productivity losses due to time off work over 6 months follow-up.

Self-reported health-related resource use and costs will be collected within the trial to determine the costs of the treatments provided by healthcare practitioners along with other healthcare utilisation due to the health condition(s) associated with absence. Self-reported information will be obtained on primary care consultations, secondary care consultations, prescriptions, hospital based procedures, nature and length of inpatient stays, and surgery. Participants will be asked to distinguish between UK NHS and private provision. The information collected from participants on occupation status, work performance, presenteeism and time off (absenteeism) will further enable the calculation of productivity costs, allowing descriptive assessment from a societal cost perspective.

4.5.4.a. Health related

Participants will be asked to report which was the main health condition that resulted in their current fit note. A list of conditions will be presented and participants asked to tick one box. Further to this, participants will be asked whether they have any chronic conditions, they will be presented with a validated list of 19 options and asked to tick all that apply. [Fortin *et al* 2017]

Perceived change in the main health condition for which the fit note was issued will be measured using the global perceived change single item question, this will be asked in all follow-up questionnaires with one question providing participants with six possible response options: completely recovered, much improved, somewhat improved, the same, somewhat worse, or much worse.

4.5.5. Sociodemographic data

Lastly, in order to describe the population, the questionnaire will include date of birth, sex (on all questionanires) and level of education (at the baseline data collection time-point only).

Table 1 Data collection schedule

Description	Measure	Baseline questionnaire	SMS text message Fortnightly for 6 months or until sustained RTW	6 week questionnaire	6 month questionnaire	MDC questionnaire (6 weeks and 6 months)
Primary outcome measure						
Number of days absence	How much time off work during the past 6 months have you had because of your health condition? Please write the total number of days, you were off work due to your health condition in the past 6 months	✓	x	✓	✓	✓
Secondary outcome measures						
Time taken to RTW	Fortnightly SMS text message asking the participant to report how many days absent they have had in the past 2 weeks until sustained RTW or 6 months follow-up	x	✓	x	x	x
Work interference	Work Productivity Activity Impairment (WPAI) questionnaire	✓	x	✓	✓	x
Work performance	Single item question (SIPQ) from the WPAI, asking participants' to what extent their health condition has impacted on their performance at work	✓	x	✓	✓	x
Mediators						

Physical health	Short Form 12 (SF12)	✓	x	✓	✓	x
Mental health	Short Form 12 (SF12)	✓	x	✓	✓	x
Depression	Patient Health Questionnaire (PHQ) 8	✓	x	✓	✓	x
Anxiety	Generalised Anxiety Disorder (GAD) 7	✓	x	✓	✓	x
Attitudes and beliefs to work questionnaire	Recently developed measure, to examine the impact of attitudes and beliefs to working on patient outcomes	✓	x	✓	✓	x
Return to work self-efficacy	Return to work self-efficacy (RTW-SE)[50]	✓	x	✓	✓	x
Physical activity level	General practice physical activity questionnaire (GPPAQ3)	✓	x	✓	✓	x
Other vocational and work related measures						
Use and content of other services providing vocational advice	Single question: Have you seen any of the following to talk about issues at work in relation to your current health condition(s)?	✓	x	✓	✓	x
Current job title	Free text used to allocate socioeconomic status	✓	x	x	x	x
Type of work	Two questions: What does the firm/organisation you work for mainly make/do? What do you mainly do in your job?	✓	x	x	x	x
Work role returned to	If you have returned to work are you	x	x	✓	✓	x

	currently: doing your usual job; on paid leave/annual leave; working fewer hours; doing lighter duties; on paid sick leave; on unpaid sick leave					
Working hours	Are you working full time ≥ 35 hours per week or part time <35 hours per week	✓	x	✓	✓	x
Working hours	Please write the total number of hours you are paid to work each week	✓	x	✓	✓	x
Work characteristics	Physical workplace demands, demand-control-support in the workplace	✓	x	✓	✓	x
Workplace characteristics	How many people are employed at your place of work?	✓	x	x	x	x
Salary	What is the total income of your household per week from all sources before taxes and deductions? (Excluding housing benefit and council tax rebate) Ranges from £5199 per year through to £39,000 or more per year	✓	x	x	x	x
Satisfaction with work	If you take into consideration your work routines, management, salary, promotion possibilities and co-workers, how	✓	x	✓	✓	x

	satisfied are you with your work?					
Commuting	How do you get to work? Walk or cycle, public transport, car (private or shared), N/A How long is your commute to work? Hours/ minutes/ N/A	✓	x	x	x	x
Health Economic Measures						
Health related quality of life	EQ-5D-5L	✓	x	✓	✓	x
Healthcare resource use	Self-reported use of other healthcare services	✓	x	x	x	x
Fit note duration	Medical record review of fit notes issued and the duration of these notes from 12 months prior to 6 months post consent to participate	✓	✓	✓	✓	x
Health related measures						
Health condition	Self-report of the main health condition resulting in the issue of the current fit note – via a list of conditions and an "other, please specify" option	✓	x	x	x	x
Chronic health conditions	List of 19 conditions participants to select those that apply to them	✓	x	x	x	x
Perceived change in the health condition for which the fit note was issued	Single item with 6 response options completely recovered, much improved, somewhat improved, the same, somewhat	x	x	✓	✓	✓

	worse, or much worse.					
Demographic data						
Age	Self-reported date of birth	✓	x	✓	✓	✓
Sex	Self-reported sex, response options of female, male, prefer not to say	✓	x	✓	✓	✓
Level of education	Indication of highest level of education from GCSE to post-graduate / professional qualifications	✓	x	x	x	x

***** Participants in the feasibility phase will complete baseline and 6 weeks questionnaire only, participants in the main RCT phase will complete baseline, 6 week and 6 month questionnaires

4.5.6. Medical record review (MRR)

In addition to the data collection from the self-report questionnaires and SMS text messages, participants will also be asked for consent for the research team to access their general practice medical record data. This request is to obtain information on fit notes issued during the timeline of this research. Records will be requested for a period of 12 months prior to entry into the study (i.e. date of consent to study participation) to 6 months after that consent to participation is given. Medical records for consenters will be extracted electronically and will be pseudonymised at source by the EMIS clinical system. Records will be exported by general practice staff with support from CRN staff or the research team as required. The pseudonymised electronic records will then be securely transferred via nhs.net email to the study team and the files stored on Keele University's secure server. Pseudonymised data will only be linked to non-identifiable data, for example, from questionnaires.

4.5.7. Follow-up data collection

The aim of the follow-up data collection in the feasibility phase is to test the processes for obtaining the data by questionnaire and text messaging, and therefore only includes data collection up to the 6 week time-point. Participants who return a correctly completed baseline questionnaire and who have provided written consent to participate, will be sent postal follow-up questionnaires at 6 weeks. The content of the follow-up questionnaires is detailed in table 1.

At follow-up, 6 weeks in the feasibility phase and 6 weeks and 6 months in the RCT, questionnaires will be mailed to all participants, those who do not respond will be sent a reminder questionnaire approximately 2 weeks later, non-responders to the reminder questionnaire will receive telephone calls approximately 2 weeks later to try to collect a minimum dataset over the phone (Minimum Data Collection (MDC)) (approximately 4 weeks after the original planned date of 6 months follow-up).

Telephone calls for MDC will be made by blinded research team members from Keele CTU. These approaches to reminders and MDC have been used previously in trials supported by Keele CTU, with good response rates.[Chesterton *et al* 2018] The Participant Information Sheet will inform participants of these follow-up reminder strategies.

4.5.8. Additional SMS text message follow-up

On return of the baseline questionnaire and provision of written consent to participate, the fortnightly SMS text message data collection will begin. Text messages will be sent fortnightly until the point of sustained RTW (defined as return to *any work* for at least 4 consecutive weeks) or until the 6-month follow-up time-point is reached. Participants will be sent 2 questions (one about their general health and one asking about their RTW status, see section 4.5.2), non-responders will be sent a second message, reminding them to reply. Where participants in the intervention arm have not achieved sustained RTW by 6 months, they will be directed, by the VSW, towards state level support to manage their health and work and as such they will be signposted to the Jobcentre Plus for advice and if appropriate, on starting an application for Universal Credit.

Keele CTU has experience of using two-way SMS text messages to collect outcome data in previous research studies.[Foster *et al* 2017, Campbell *et al* 2016] The software development team within the CTU will support this data collection, and will make use of an in-house bespoke database-driven system to manage the sending and receiving of SMS text messages. The participant will respond to the third party SMS provider. The CTU system will poll (ask) the third party SMS provider for returned SMS text messages. On processing of returned SMS text messages, the system will import these into the study database and process the response according to the business logic defined in the project. Interception of the original message by a third party would reveal only what the questions were that were being asked, whilst interception of the response would only yield string data in the form of numbers or dates.

A number will be provided to enable participants to contact Keele CTU if they have queries relating to the SMS text messaging. Additionally, if there is no response from a participant for two

consecutive weeks, a member of Keele CTU may contact the participant to confirm that we have the correct contact details and that the participant is able to use the SMS messaging service.

4.6. Linked semi-structured interviews

The aim of the interviews in the feasibility phase is to understand the participants' experiences of being invited to participate, the delivery of the vocational advice intervention, their engagement with it and the usefulness and acceptability [Sekhon *et al* 2017] of it in supporting them to RTW. Where improvements in the recruitment process and or the delivery of the intervention are identified these will be used to support the development of the RCT processes.

4.6.1. Identification of participants to be invited for interview

All participants in the feasibility study will be invited to participate in an interview about their experiences of participating in the study (n=30) with the aim to conduct up to 20 interviews.

4.6.2. Invitation and consent to interview

Participants will be sent an invitation letter and participant information sheet explaining the purpose and structure of the interview, confidentiality and anonymity, data storage and archiving. A reply slip will also be included for patients to return in a pre-paid envelope to notify the research team that they are willing to participate in an interview and to provide contact details. A member of the research team will then telephone the patient to arrange a suitable date and location for the interview to take place; for instance, the participant's home, or by telephone/videoconferencing depending upon the participant's preference and COVID-19 restrictions. The research team will ensure the completion of the interview consent form prior to the start of each interview, either through written consent where the interview is conducted face to face or audio-recorded where the interview takes place over the telephone or via videoconference. Consent will also be reaffirmed verbally at the end of each interview.

4.7. Data collection

Semi-structured interviews with up to 20 participants from the feasibility study will be undertaken, the final number of interviews will be guided by data saturation, defined in terms of 'informational redundancy' – the point at which additional data no longer offers new insights.[Sandelowski 2008] Topic guides will be used in interviews, informed by the objectives (see section 2.1.1). The topic guides will be used to prompt participants about a range of aspects relating to their experience of participating in the feasibility study, including (but not limited to) the following;

- The acceptability of the participant information about the study and the intervention
- The experience of the recruitment process
- Acceptability of SMS text messages and study questionnaires, e.g. wording, length, frequency etc.
- The acceptability and usefulness of the intervention e.g. suitability of the content, timing and usefulness of the vocational support, delivery of the intervention
- Impact of COVID-19 on work situation and relevance of the WAVE intervention
- Perceptions of how the vocational support intervention did or did not support their RTW and how this could be improved.

As these will be semi-structured interviews, the interviewer (a researcher trained in qualitative research methods) will have the flexibility to follow-up on other relevant topics that arise throughout the course of the interviews. Topic guides will be iteratively revised throughout the data-collection and analysis processes in light of emerging findings.

5. Mixed methods process evaluation

The process evaluation will utilise data collected by questionnaire and by the interviews to answer the objectives of the feasibility study (see section 2.1.1).

5.1. Quantitative analysis

Analysis of the single group feasibility study will report the numbers and proportions of potentially eligible patients identified, invited and consenting to participate, as well as the engagement with the vocational support intervention (the take up of the offer of the intervention, and the steps of the intervention that were taken up). We will also examine the CRFs describing the intervention for each of the 30 participants to assess the level of intervention offered and delivered i.e. steps 1-3 and their contents, and the number and duration of phone calls and face to face / video consultations. The CRFs will also be used to examine intervention fidelity by assessing the proportions of consultations in which the expected content of the intervention was delivered (using a checklist of expected content). Fidelity will be further tested by analysis of a sample of audio-recorded consultations, again using a checklist to assess whether consultations cover the expected content of the intervention.

5.2. Qualitative analysis

Analysis of consultation recordings

A sample of up to ~10 recorded VSW consultations in the feasibility phase will be transcribed and subjected to in-depth analysis using targeted conversation analysis techniques (Sidnell and Stivers, 2015) for rapid investigation of how the intervention content is delivered. This will provide a more in-depth understanding of intervention fidelity. Any areas identified through this analysis in which VSWs may be having difficulties successfully delivering the intervention will then be discussed amongst the trial team, and a plan developed for making any amendments to the training ahead of the RCT to support VSWs to overcome these difficulties.

Interview analysis

All interviews in the feasibility phase will be audio-recorded, fully transcribed and then cleaned/ anonymised. An inductive, exploratory framework will be adopted using thematic analysis, and influenced by grounded theory [Glaser *et al* 1999]. First, a sample of early transcripts will be independently coded by two researchers with experience in qualitative analysis, and a coding framework agreed upon, which will then be applied in subsequent coding. Coded data will be analysed by the qualitative social science researcher and a second research team member independently to develop categories and themes, to be discussed at team meetings. The constant comparison method [Corbin *et al* 1990] will be used in the analysis, looking for connections within and across interviews, and across codes, highlighting data consistencies and variation. Analysis will be an iterative process, with emergent findings used to further refine topic guides for subsequent interviews. Comparisons will then be made using a framework approach [Spencer *et al* 2014] between the experiences of participants with different health conditions looking for similarities and differences in the separate accounts particularly related to how the methods of identification, recruitment and intervention delivery can be improved. We will also use the acceptability framework of Sekhon *et al* (2017) to sensitise the analysis.

6. Feasibility study reporting

The findings of the feasibility study will be reported in order to identify, evaluate and action any changes to the WAVE study processes or intervention prior to commencement of the RCT. Decisions will be taken on the following aspects in particular;

- The process through which patients are identified i.e. use of the automated health informatics IT protocol within general practice consultations (see section 4.3.1) and back dated searches of the electronic medical record (see section 4.3.2)
- The processes through which patients are invited and recruited including the content of the PIS, the eligibility criteria and the processes of completion and return of the baseline questionnaire and consent form (see section 4.4)

- The acceptability of, and engagement in, the vocational support intervention including the timing, delivery method, steps delivered and content
- The processes of data collection including the SMS text-messaging system and study questionnaires.

To ensure that decisions are made appropriately about whether to proceed to the next phase, the internal pilot RCT phase, we propose the following stop/amend/go criteria at this point (end of feasibility study phase): i) recruitment uptake <25% of those eligible and expressing an interest in the study (Red), 25%-49% (Amber), ≥50% (Green); (ii) intervention fidelity % of patients who have at least one contact with a VA <40% (Red), 40-65% (Amber), >65% (Green). The stop/amend/go criteria have been agreed with the independent oversight committees (Trial Steering Committee and Data Monitoring Committee) and these committees will be involved in the decision about progression to the RCT phase.

Where there are changes to the proposed methodology of the trial that require regulatory approval these approvals will be sought before the randomised trial commences recruitment.

7. Randomised controlled trial (RCT) with internal pilot

The feasibility phase will be followed by a pragmatic, multi-centre, two-arm, parallel group, randomised (1:1) controlled trial (RCT) to determine the effectiveness of adding the brief vocational support intervention to usual primary care, in reducing number of days absent from work over 6 months in patients who receive a fit note when consulting at their general practice. The RCT also includes a full health economic analysis and process evaluation.

7.1. Methods

The methods used for the RCT with internal pilot will be the same as those used in the feasibility study but will include the additional 6 month follow-up questionnaire.

The following aspects will remain the same: Inclusion/exclusion criteria (4.2); Identification of potential participants (4.3); Invitation and recruitment (4.4); Data collection process but with the addition of the 6 month questionnaire with the same reminder processes in place (4.5); Linked semi-structured interviews (4.6). Therefore the following methods start at the point at which a participant returns their baseline questionnaire confirming eligibility and consent to randomisation.

7.2. Randomisation

On confirmation of eligibility and receipt of a completed consent form participants will be randomised by Keele CTU to either usual primary care or usual primary care plus the vocational support intervention arms of the study by computer-generated stratified block randomisation (ratio of 1:1). Stratification variables will be centre (Keele, London, Wessex) and main health condition resulting in the time off work (MH, MSK, other). All participants will be mailed a letter informing them whether they have been randomised to either the usual care or to usual care plus the vocational support intervention arm of the study. Those participants randomised to the vocational support intervention arm will be telephoned by the VSW to begin the delivery of the intervention. A letter will be sent to the clinicians in participating practices of all randomised participants informing them of their patient's participation and the outcome of the random allocation.

7.3. Blinding

Participants, their treating clinicians and VSWs cannot be blinded to allocation due to the nature of the intervention. Keele CTU staff who may need to contact participants for MDC phone calls will be blinded to allocation. The data will be analysed independently by two statisticians one of whom will be blinded to intervention allocation the other statistician will be unblinded to allow intervention delivery details and content of CRFs to be reported to the Trial Steering Committee (TSC) / Data Monitoring Committee (DMC) as required.

7.4. Control and intervention arms

Control: Usual Primary Care

Patients randomised to receive usual primary care will continue to be offered care as usual for their health and vocational needs. For most patients, this will comprise usual clinical care, without formal vocational advice. Information on usual care received will be collected through the questionnaires (to include questions about other vocational advice or occupational health services received) and through review of the general practice medical record data to collect data on further issue of fit notes.

Intervention: Usual primary care plus the vocational support intervention

Participants who are randomised to the intervention arm will be offered usual primary care as well as the vocational support intervention. The intervention will be based on that developed and successfully delivered in the Study of Work and Pain (SWAP) trial,[Wynne-Jones *et al* 2018] comprised of a stepped care intervention based on the principles of case management.[Ross *et al* 2011] A full description of the anticipated content of the intervention was provided in section 3.4.2, the process by which the vocational support intervention will be delivered if provided in section 3.5, and the training for the VSWs to support their delivery of the intervention is detailed in section 3.6.

8. Linked qualitative study

The broad aim of the qualitative study is to understand how the perspectives and experiences of patients, VSWs, healthcare professionals, and employers/line-managers/supervisors influence their decision-making around work absence and RTW planning, experiences of receiving and delivering the vocational support intervention and its delivery in practice.

8.1. Identification of participants for interviews

Participants' questionnaires at 6 weeks will be screened to enable a purposive sampling frame to be applied. A range of participant characteristics will be sampled for, including: age, sex, health condition (MH, MSK, other condition), centre (Keele, London, Southampton), job type, duration of work absence, level of engagement with the vocational advice intervention (i.e. steps 1-3), and RTW status, with the aim of exploring the experiences of a broad range of participants about the vocational advice intervention and its impact on their progress to RTW.

8.2. Invitation to participate in an interview

The processes for inviting potential participants to interview will follow that set out in the feasibility study in section 4.6.2. Potential participants will also be informed when invited that if

they agree to be interviewed, we will also be asking for their permission to contact their employer, line-manager or supervisor (depending on who is most appropriate for their workplace), and their primary care clinician, to invite them to take part in separate, matched interviews. These matched interviews will discuss the individual participant case, as well as accessing employer and clinician views on managing sickness absence more broadly. Potential participants will, however, be informed that they can still take part in an interview even if they do not agree to us contacting their clinician or employer. Those participants who do agree to this at the time of their interview, will be asked to provide the name of their primary care clinician and their employer's, line-manager's or supervisor's contact details. Following the interview with the participant, the employer and clinician will then be contacted either by telephone, email or post, following which an invitation letter and information sheet about the interview will be emailed or posted to them. A member of the research team will then contact the interviewee to make arrangements for the interview.

In addition to these matched participant-clinician-employer interviews, other clinicians from participating practices who are not matched to a participant being interviewed will also be invited to participate in an interview, in order to explore general views on decision-making relating to patient work absence. Those clinicians who have consulted with a number of patients recruited into the trial will be purposively sampled, to allow them to reflect on whether participation in the trial has resulted in any changes to their own practice. All VSWs will also be invited to participate in an interview. Both of these participant groups will be sent an invitation letter and participant information sheet about the interview, following which a member of the research team will contact them to make arrangements for the interview. In the case of all interviews, consent will be taken prior to the interview and reaffirmed verbally following the interview.

8.3. Data collection

Semi-structured interviews with up to 20 trial participants, and up to 20 VSWs, healthcare professionals and employers/line-managers will be undertaken, the final number of interviews will be guided by data saturation, defined in terms of 'informational redundancy' – the point at which additional data no longer offers new insights.[Sandelowski 2008] Topic guides will be used in interviews, informed by the objectives (reported in section 2.1.3) and focusing on understanding how the intervention works using the logic model as a further guide to the topics included. Separate topic guides will be developed for trial participants, VSWs, healthcare professionals and employers'/ line-managers' interviews. The topic guides will be used to prompt participants about

a range of aspects relating to their experience of work absence including (but not limited to) the following;

- Perspectives and experiences of trial participants, VSWs, healthcare professionals, and employers/line-managers regarding work absence
- The influences on each groups' decision-making around sickness absence
- The VSWs' experiences of delivering the intervention; in particular, how they supported participants through the RTW process including their decision-making about the steps of intervention delivered (i.e. steps 1-3)
- The participants' experiences of engagement in the vocational advice intervention, acceptability, mode of delivery, and whether/how it supported their RTW
- Participants' decision-making in deciding to RTW
- Primary care clinicians' views about the impact of the intervention on their own practice; e.g. number of fit notes given, patients re-consulting, discussions with patients about work absence in consultations
- Impact of COVID-19 on the suitability of the WAVE intervention.

'Matched' participant-healthcare professional-employer interviews will focus on the individual participant case, exploring the management of work absence and impact of the intervention on decision-making about RTW for that particular participant.

9. Analysis

There are four parts to the proposed trial analysis focusing on specific aspects of the data collection and processes: the internal pilot RCT phase, main RCT phase (including mediation analysis), health economic data analysis and qualitative data analyses.

9.1. Internal pilot

The internal pilot trial will assess recruitment and intervention fidelity in those recruited over the first 4 months, and focusing on the proportion with follow-up data at 6 weeks. It is anticipated recruitment rate will be approximately 4 patients/practice/month in the internal pilot and achieving 80% follow-up in the primary outcome at 6 months. We will scrutinise (i) recruitment (target versus actual, % eligible, % consenting and randomised), (ii) intervention fidelity, and (iii) follow-up rate at 6 weeks. A 'stop (Red)/ amend (Amber)/ go (Green)' set of progression criteria will be finalised with the Trial Management Group and Trial Steering Committee (TSC) in line with recent guidance [74] but we currently propose these to include: (i) recruitment uptake <50% of those

eligible and who express an interest (Red), 51%-74% (Amber), ≥75% (Green); (ii) engagement with the intervention, % of intervention arm participants who have at least one contact with a VSW <40% (Red), 40-65% (Amber), >65% (Green); (iii) primary outcome data at 6 weeks follow-up rate <60% (Red), 60-80% (Amber), >80% (Green). A decision to continue to the main trial would be made if all progression criteria are met at the 'Green' level, and to continue but with some adjustments if any criteria are at least 'Amber'; the trial may be stopped if any of the criteria are 'Red' and the Trial Management Group (TMG) and TSC agree they cannot be addressed.

9.2. Main trial

Baseline participant characteristics will be summarised according to the nature of the data (mean/standard deviation for normally distributed variables; median/inter-quartile range for skewed numerical data; frequency/percent for categorical variables) – overall, and by treatment arm (no formal statistical testing will be carried out). An intention-to-treat approach will be carried out as the main approach to analysis: analysing participants as per randomised allocation. This is in line with the pragmatic nature of the trial – allowing for infrequent referral to occupational health within both arms and a lack of contact with the vocational support intervention in a small proportion of those participants in the intervention arm.

For the primary outcome measure of time off work we will present descriptive statistics on both mean (and median) number of days off work with standard deviation (and interquartile range) – for the time intervals baseline to 6 weeks and 6 months follow-up, by trial arm. The inferential analysis will be carried out by negative binomial (or Poisson) regression models adjusting for age, sex, centre, main health condition for which the fit note was issued (MH, MSK, other) and time off work due to health condition in the 6 months prior to trial participation (fixed effects). If there is over-dispersion (skewness) in the outcome data, then the negative binomial model will likely be preferred to the Poisson model; the goodness of fit of each model will be assessed to determine the most appropriate model for the analysis through scrutiny of the likelihood-ratio test and Akaike/Bayesian Information Criterion (AIC/BIC). The estimated effect will be presented as an incidence rate ratio; the results will be given as the point estimate with 95% precision interval and associated p-value. The primary endpoint evaluation will be number of days off work over the 6 months follow-up, with days off work over the initial 6 weeks follow-up as a secondary endpoint.

Similarly, descriptive summaries of data (mean (SD) / median (IQR) / frequency count (percent)) by trial arm will be presented for secondary outcomes. Proportions of participants accessing each step of the intervention (1, 2 and 3) and the content of the intervention as detailed on CRFs will be

reported. A mixed model approach will be carried out for between-arm estimation of mean differences (for numerical outcomes) or odds ratios (for categorical outcomes) through linear or logistic link functions, respectively. The regression models will include the same covariates as outlined above for the primary outcome analysis and additionally the corresponding baseline value (as appropriate) e.g. baseline RTW self-efficacy score for evaluation of between-arm difference in mean RTW self-efficacy at follow-up. Time to sustained RTW data, collected by fortnightly SMS text messages, will be evaluated through survival analysis methods: life table and Kaplan-Meier descriptive summaries and Cox regression modelling with covariates as detailed above.

A complier average causal effect (CACE) evaluation will be undertaken to obtain unbiased estimation for the comparison of the primary outcome for those participants in the intervention arm who had at least one contact with the VSW versus balanced participants in the control arm. A small number of pre-specified subgroup analyses will be carried out evaluating whether between-arm differences in the primary outcome measure (number of days off work over 6 months) contrast across the following baseline subgroup variables: baseline main health condition resulting in the fit note (MSK, MH, other) and duration of work absence in previous 6 months. Statistical estimates will be obtained through including interaction terms for trial arm × baseline subgroup within the statistical model of treatment effect. All statistical analyses are focused on superiority testing based on 5% two-tailed significance level.

Analyses will be carried out blind to intervention allocation (with the exception of the CACE analysis and CRF data analysis describing the content of the vocational advice intervention) and double-analysed by two statisticians. Data collection, checking and verification will be performed according to Keele CTU Standard Operating Procedures (SOPs) to ensure rigour in the data for analysis. A detailed Statistical Analysis Plan (SAP) will be completed with guidance from the DMC and TSC to ensure transparency in the statistical analysis of the trial.

9.3. Mediation analysis

Mediation analysis is a statistical approach for testing hypothesised causal pathways between variables thought to be important in explaining treatment outcome. Testing such causal mechanisms is an important aspect of process evaluation.[Moore *et al* 2015] Variables hypothesised to be key mediators of the intervention (e.g. RTW self-efficacy; see the full list in section 4.5.3) will be finalised through the intervention adaptation in the feasibility phase. In the trial, data on these variables and on the primary outcome will be collected at baseline, 6 weeks and 6 months. Change in each mediator between baseline and each follow-up point will be described.

Multilevel causal modelling techniques will then be used to identify the proportion of the intervention effect on days absent from work that is explained through change in the potential mediators (indirect effects). Each mediator will be first analysed separately, then combined into a single multiple mediation model to assess the combined effect of the potential mediator variables on the outcome of days absent from work over 6 months. Latent growth curve models will be used for this analysis as they allow for all three time points to be used within the analysis. These indirect effects on outcome will be expressed as a regression coefficient with bootstrapped 95% CI.

9.4. Health economic analysis

The health economics analysis will comprise of two approaches, within-trial analysis over 6 months follow-up using individual-level costs and outcomes and model-based analysis to extrapolate the potential cost-effectiveness of the addition of the vocational advice intervention over a longer time frame.

9.4.1. Within trial-analysis

An economic evaluation will be undertaken alongside the trial to estimate the cost-effectiveness, cost-utility and cost-benefit (including return on investment) of the addition of the vocational advice intervention to usual primary care, over 6 months follow-up. A cost-consequence analysis will initially be reported, describing all the important results relating to resource use, costs and consequences, across the full range of clinical and economic outcomes. Subsequently, three methods of economic evaluation will be used.

i) A cost-effectiveness analysis undertaken from a healthcare perspective to determine the cost per additional day of work absence avoided.
ii) A cost-utility analysis from a healthcare perspective (base-case) and societal perspective (secondary analysis) to determine the cost per QALY gained.
iii) A cost-benefit analysis undertaken from a broad societal perspective to calculate the net societal benefit of the intervention, by subtracting the difference in direct healthcare costs (costs) between the arms from the difference in indirect productivity costs (benefits) between the arms. This will also allow return on investment to be calculated by dividing the net benefits of the VSW intervention (gain minus cost) by the net costs of the intervention.

Resource use and costs: Healthcare resource use will be collected using data from the 6 month postal questionnaires and general practice medical record reviews will provide data on fit notes

that may have been issued. Health sector costs will include primary care and secondary care contacts such as GP and practice nurse consultations/home visits, medications, contacts with other healthcare professionals, NHS and private outpatient visits and inpatient stays and use of other vocational advice services. Information on patient-incurred costs will also be collected, such as over-the-counter purchases. Questions on time off work, presenteeism and occupation will provide information required to calculate the indirect (productivity) costs (benefits), and further details are given in the next section on outcomes. In order to obtain the cost of the vocational support intervention, information on number and duration of contacts with the VSW (telephone calls, videoconference calls or face-to-face visits) will be obtained for each participant and unit costs applied to calculate the overall cost of the intervention. The costs of training and mentoring VSWs, and intervention delivery costs dependent on different types of VSW (e.g. those who are nurses, IAPT practitioners and counsellors, physiotherapists, Council employment support workers) will also be calculated to provide decision-makers with the cost of setting up the service and for inclusion in a sensitivity analysis. Resource use will be multiplied by unit costs obtained from standard (national) sources and healthcare providers. Due to the lack of nationally representative unit cost estimates for private healthcare, this care will be costed as the NHS equivalent.

Outcomes: The outcome measure for the cost-effectiveness analysis is self-reported number of days absent from work over 6 months. For the cost-utility analysis, the EQ5D-5L questionnaire will be completed by participants at baseline and 6 months,[Herdman *et al* 2011] in order that QALYs over the 6 month time period can be calculated for each participant, using the area under the curve method. The crosswalk value set will be applied to patient responses to obtain utility scores, in line with current NICE recommendations.[van Hout *et al* 2012] The more recent English value set will be used in a secondary analysis.[Devlin *et al* 2015]

In the cost-benefit analysis, benefits will be estimated from the data on productivity losses. These will be calculated using data collected on employment status at every time-point and number of days off work. Information on occupation, further details of typical work activities and the nature of their employment (full time or part time) will be requested. The average wage for each respondent will be identified using UK Standard Occupational Classification coding and annual earnings data for each job type [Office for national statistics Annual survey of hours and earnings, Office for national statistics Standard occupational classification]. The analysis will use the human capital approach, and the self-reported days of absence will be multiplied by the respondent-specific wage rate. The human capital approach assumes that the value of lost work is equal to the

amount of resources an individual would have been paid to do that work, and values productivity losses as a result of morbidity (or mortality) by measuring time lost from work and multiplying this with the gross wage of the person. Whilst there is no standard tool for capturing the costs of presenteeism, we propose to use the Single-Item Presenteeism Question (SIPQ) contained within the Work Productivity and Activity Impairment Questionnaire (WPAI).[Kroenke *et al* 2001] Our previous work has demonstrated this question to be both valid and responsive in patients with MSK pain and other conditions [Kigozi *et al* 2014, Wynne-Jones *et al* 2009]. This estimation of perceived percentage loss in productivity can be applied to person-specific wage rates using the human capital approach. Given the many uncertainties in the measurement of costs due to presenteeism, this will be presented as part of a secondary analysis.

The health economic analysis will estimate the incremental cost-effectiveness, cost-utility and the cost-benefit of the intervention in comparison with usual care. Costs for the intervention and usual care arms will be presented for each broad cost category (healthcare costs, patient-incurred costs, productivity costs) and disaggregated within each of these cost categories.

The data for costs are likely to have a skewed distribution therefore a non-parametric comparison of means (e.g. bootstrapping) will be undertaken to estimate confidence intervals around costs. Where there is missing data on resource use or quality of life outcomes, multiple imputation techniques will be carried out to ensure that all trial participants are included in the final analysis. Adjustment for baseline covariates will focus on the same variables as outlined for the primary analysis.

The robustness of the results will be explored using sensitivity analysis. This will explore uncertainties in the trial based data itself, methods employed to analyse the data, for example, an available case analysis as an alternative to using a multiple-imputed dataset. Uncertainty will be explored through the use of cost-effectiveness acceptability curves (CEACs); these plot the probability that the addition of the vocational support intervention to usual care is cost-effective against threshold values for cost-effectiveness.

9.4.2. Model-based analysis

If the trial finds the addition of the vocational advice intervention is more effective than usual care alone, decision modelling will also be undertaken to extend the within-trial results beyond the 6 months follow-up time-point. The purpose of the model is to extrapolate costs, time off work

outcomes and QALYs over a longer time horizon to calculate the long-term cost-utility and cost-benefit, with discounting of costs and outcomes at 3.5%. Whilst the full details of the modelling methodology will be determined in consultation with experts in the trial and a review of previous models in the literature [Squires *et al* 2012] this is likely to be a Markov model. This type of model allows the representation of health states related to the health conditions and recurrence of symptoms or episodes of work absence. Once the characteristics of the trial participants are known, for example, age and the range of clinical conditions leading to time off work, then decisions can be made on an appropriate time horizon and also if individual level simulation is required.

In addition to trial data, the model will be populated with data from existing literature on long-term work outcomes, the natural history of the main health conditions included within the model, quality of life, costs and national data on all-cause mortality. The model will be subject to extensive deterministic sensitivity analysis by changing individual parameter values and changing model assumptions, and probabilistic sensitivity analysis to simultaneously incorporate all parameter uncertainty. Cost-effectiveness planes and cost-effectiveness acceptability curves will be presented to show the probability the intervention is cost-effective at different cost/QALY thresholds. Where appropriate, subgroup analyses may be considered for different patient groups (eg. those with differing time-off-work at baseline, those with different types of job). These will be determined with input from the TSC and detailed in the detailed analysis plan. All reporting of the methods and results of the health economics analyses will be conducted in line with the recommendations in the CHEERS checklist [Husereau *et al* 2013].

9.5. Linked semi-structured interview analysis

Interview transcripts form the data for analysis, which will mirror the approach outlined above for the feasibility study, combining, firstly, thematic analysis, influenced by grounded theory [Glaser and Strauss 1967], and then a framework approach [Spencer *et al* 2014]. Data from each of the different groups (participants, VSWs, healthcare professionals and employers/line-managers) will be analysed separately; the findings from each dataset will then be mapped onto one another, to explore the similarities and differences in the identified themes. Comparison will also be made both within and across 'matched' participant-clinician-employer cases, informed by the framework approach.

10. Sample size

The trial is powered to detect a 25% reduction in days off work over 6 months between the intervention arms, equating to an Incidence Rate Ratio (IRR) of 0.75 (e.g. mean days off work reduces from 30 days in control arm to 22.5 days in intervention arm). A sample size of 720 gives 80-90% power to detect an IRR of 0.75 based on a 5% two-tailed significance test and assumed dispersion parameter of 1.4 (derived from the previous SWAP trial) allowing for 20% loss to follow up [Wynne-Jones *et al* 2018].

10.1. Estimated recruitment rates

Based on an annual prevalence of 4% of fit notes issued [Wynne-Jones *et al* 2009] and estimates from our previous trials [43,53-55] we anticipate that a general practice population of 60,000 registered patients will be required (assuming an average practice size of 5,000 registered patients, and 12 general practices). We anticipate mailing approximately 4,800 invitation letters, and that 30% will respond and express an interest in participating (1,440). Of those who express interest it is conservatively estimated that 50% will be randomised (720). To achieve the sample size of 720 participants we aim to recruit 4 patients/per practice/per month over 18 months, this figure takes account of a phased start to recruitment, a build-up of recruitment in each practice and seasonal drops in recruitment.

11. Data handling and archive

Data management will be carried out in accordance with a Study Data Management Plan designed by the TMG in accordance with Keele University Health and Social Care Research Quality Management System Standard Operating Procedures (HSCR SOPs). Questionnaires will be date stamped on receipt at the Keele CTU. Questionnaire data will then be logged as returned on a management database and the participants' responses entered / scanned into a database; the databases will be tested *a priori* for functionality and reliability. The study statistician will determine coding of questionnaire items, in accordance with standardised coding procedures as per relevant SOPs to facilitate data entry. Keele CTU staff will enter / scan data and data entry checks will be carried out as per relevant SOPs to ensure quality of data entry.

The study is designed so that all participant personal data (e.g. names, addresses) are located on a database stored within Keele University's secure network which can only be accessed by two factor authentication, restricted to approved personnel. Furthermore, all data used for analysis will be kept separate from participant personal data to ensure anonymity to meet the necessary

standards of Keele University data security policy. Similarly, all hard copy information (e.g. signed consent forms, questionnaires, CRFs) will be stored securely in accordance with SOPs. Hard copy material will be stored for a minimum of ten years after the full research programme has completed. After that period all hard copy material will be destroyed as per SOPs. All confidentiality arrangements adhere to relevant data protection regulations and guidelines (General Data Protection Regulation (GDPR), Caldicott, General Medical Council (GMC), Medical Research Council (MRC) Research Governance Framework) and the Chief Investigator and Study Statistician (Data Custodian) have responsibility to ensure the integrity of the data and that all confidentiality procedures are followed.

Data collected about the vocational advice intervention (CRFs) will be sent to Keele CTU from centres using a secure method (e.g. scanned and e-mailed via NHS-to-NHS e-mail accounts, or posted in pre-paid return envelopes).

Any subsequent requests for access to the data from anyone outside of the research team (e.g. collaboration, joint publication, data sharing requests from publishers) will follow the Keele University's data sharing procedure. Personal data about participants will not be provided to legal representatives where a participant is involved in a workplace grievance or litigation.

11.1. Qualitative data handling and archiving

As with the management of data from the trial, all procedures will be carried out in accordance with Keele University HSCR QMS SOPs. The digital audio-recordings for the qualitative interviews including the recordings of VSW-patient appointments will be uploaded to secure storage at Keele CTU as soon as possible, with access limited to relevant research team members. Once safely stored, the data on the digital-recorder will be deleted. Recordings will be sent for transcription via a secure upload system to the CTU's supplier with whom there is a contract in place around confidentiality and security. Transcripts will be returned password-protected, uploaded to the appropriate storage and deleted from email. Transcripts will be cleaned and anonymised prior to analysis, through replacing individuals' names and place names with pseudonyms and removing any other potentially identifiable details. Hard copies of anonymised transcripts will be labelled with the study ID number and stored securely within Keele CTU.

Consent forms and contact details will be stored separately to the audio-recordings and anonymised transcripts. Only anonymous data will be used in publications and presentations. Archiving will be in accordance with Keele University HSCR QMS SOPs.

12. Study monitoring and audit

12.1. Study management

The study Chief Investigator (CI) is responsible for the conduct of the study and will convene the TMG comprising of members of the research team and Keele CTU. Trial management will be carried out in accordance with Keele University HSCR QMS SOPs. The TMG will meet at regular intervals throughout the study and will be responsible for the set-up, start, ongoing management and monitoring, promotion of the study, analysis and interpretation of the results. The TMG will oversee: the protocol development; CRF development; obtaining regulatory approval and site set-up; monitoring and managing funding in association with Keele University finance staff; reporting of related serious adverse events (see section 12.5) to the Sponsor, TSC and REC; monitoring of screening, recruitment, and follow-up procedures; data collection and study specific software development; completing regulatory reporting requirements. The TMG members include the CI, Associate Investigator (AI), study co-applicants, and a CTU senior trial manager, trial manager, and statistician plus other stakeholders as required.

12.2. Trial Steering Committee (TSC)

An independent TSC has been appointed according to the funder's requirements and approved by the funder and will be responsible for the scientific conduct of the trial. It will receive independent reports, at least annually, from the DMC and will provide expertise and oversight for the research dissemination plan. The TSC includes an Independent Chair, and both independent patient/lay and senior statistical representation, providing overall supervision of the study, meeting face to face by teleconference or videoconference over the course of the trial as needed.

12.3. Data monitoring committee (DMC)

An independent DMC has been appointed according to the funder's requirements and approved by the funder. The DMC will review the safety of the trial including monitoring of the trial throughout data collection, scrutinising recruitment, randomisation, protocol adherence and follow-up and assess relevant adverse events. The DMC will report progress including any safety concerns to the independent TSC.

12.4. Monitoring arrangements

Study monitoring will be carried out in accordance with a Study Monitoring Plan and Keele University HSCR QMS SOPs which lay out the procedures for monitoring consent forms, data collection, CRFs, protocol compliance and data management and entry procedures.

Study data will be monitored for quality and completeness by Keele CTU. All participants must have a completed baseline questionnaire and consent form before they can be randomised and be contacted by the VSW to deliver the intervention. Keele CTU and Keele University as the Sponsor will reserve the right to conduct source data verification exercises on a sample of participants, which will be carried out by staff authorised by Keele CTU and the Sponsor.

12.5. Safety reporting

The vocational advice intervention being delivered is anticipated to be low risk, therefore related adverse events, should any occur, are likely to be uncommon and generally minor. The VSWs will be asked to report unexpected events they become aware of during the study. Reporting procedures will be made clear during the VSW training and will be contained in site files for all those involved in the study.

We understand that work and time off work may be sensitive topics for some patients, particularly those with mental health conditions. Therefore, a risk protocol will be in place which will outline how VSWs respond where participants' express thoughts or ideas of self-harm or are thought to be at risk (see Appendix 3). Clinical input, liaison with participants' GPs and support for the VSWs after incidents where participants may be distressed will be provided by medically qualified members of the research team.

Should an Adverse Event (AE) occur the Keele University HSCR QMS SOP relating to the reporting of such events will be adhered to.

Adverse events

An Adverse Event (AE) is any untoward medical occurrence in a study participant. A Serious Adverse Event (SAE) is defined by the Health Research Authority (HRA) as an untoward occurrence that:

(a) results in death;

(b) is life-threatening;

(c) requires an unscheduled hospitalisation or prolongation of existing hospitalisation;

(d) results in persistent or significant disability or incapacity;

(e) consists of a congenital anomaly or birth defect; or

(f) is otherwise considered medically significant by the investigator.

Safety Reporting for WAVE

Anyone who is involved in the trial is required to report any AE as defined below:

> **WAVE reportable AEs**: All AEs which are perceived to be related to the participant's involvement in the trial or to the intervention (the vocational advice intervention) in the trial.

Reporting will follow the process outlined below.

Safety Reporting Process

Anyone who is involved in the WAVE trial (including VSWs, GPs and local Trial Managers) will be asked to record events or concerns about the safety of participants that arise as a result of the trial. Reporting procedures will be made clear during VSWs training and will be contained in the site files available for all those involved in the trial. An additional risk protocol will be in place which will outline how VSWs respond where participants express thoughts or ideas of self-harm or are thought to be at risk [Appendix 3]. Clinical input, liaison with participants' clinicians' and support for the VSWs after incidents where participants may be distressed will be provided by medically qualified members of the research team.

All **WAVE reportable AEs** occurring from the point when participants have consented to participate must be notified to the Trial Manager within 24 hours of becoming aware of the event:

- Via telephone: Keele CTU +44 (0)1782 732950

  AND / OR

- Via email: sch-tr.wave@nhs.net

The Trial Manager will contact the person who identified the AE and will record the details of the event in an appropriate AE form within 24 hours of being informed. The Trial Manager will record the AE in the study's AE log and report it at the next Trial Management Group meeting, as per Keele University HSCR QMS SOP.

The Trial Manager will also send the completed adverse event form to the WAVE AE review team for consideration and decision making on AE categorisation based on seriousness, relatedness and expectedness and causality, as appropriate. The WAVE AE review team is composed of the Chief Investigator and a WAVE clinician. Clinician cover will be in place if necessary.

If the WAVE reportable AE is confirmed as an AE or related AE, the Trial Manager will file completed case report form(s) into the Trial Master File and inform the relevant person(s) of the AE decision outcome. These will not be reported to the Sponsor, as per Keele University HSCR QMS SOP.

If the WAVE reportable AE is confirmed as a related unexpected SAE, the Chief-Investigator or delegate will inform the Sponsor, who will report this to REC within 15 calendar days of becoming aware of the event. In addition, the Non-CTIMP Safety Report Form will be completed and sent to HRA, TSC and DMC chairs as soon as possible and within the REC reporting timelines. The Trial Manager will file the Safety Report Form and associated documents in the Trial Master File. Where required participants and/or appropriate person(s) are notified of the SAE assessment outcome.

Responsibilities for safety reporting

Person(s) involved in the WAVE Trial (including VSWs, GPs and local Trial Managers) are responsible for:

- Ensuring they are aware of the safety reporting procedures as described in the protocol and site file
- Ensuring that all **WAVE reportable AEs** are reported to the trial Manager (at Keele University) immediately or within 24 hours of becoming aware, as per protocol

The WAVE AE review team (CI and WAVE Clinician) are responsible for:

- The oversight of the safety of patients participating in the trial, including an ongoing review of the risk/benefit
- Using judgement in assigning seriousness, relatedness, expectedness and causality
- Review of all AEs as detailed in the study monitoring plan

The sponsor is responsible for:

- Expedited reporting of Related SAEs to the HRA.
- Reporting of confirmed related SAEs to Keele University's Health Research Oversight Committee (HROC) in accordance with their requirements.

12.6. End of study

The end of the study is defined as the extraction of data from the last medical record of the last participant to be followed-up in the study. The HRA will be notified of the end of the study in accordance with Keele University HSCR QMS SOPs.

13. Ethical and regulatory considerations

13.1. Research Ethics Committee (REC) review and reports

Keele CTU will support obtaining research ethics and governance approvals, ongoing management including VSW training, monitoring reports and promotion of the research study.

13.2. Participant involvement

Participants will need to take some time to complete each of the questionnaires, should participants not return the questionnaire, attempts will be made to collect minimum data (MDC) by telephone.

The engagement with the vocational advice intervention will differ for each participant. But as an estimate, based on the SWAP trial, the initial phone calls to the participants are anticipated to take approximately 15 minutes and any face to face / video consultations to take approximately 1 hour.

It is estimated that interviews with participants will last up to one hour, and the VSW, healthcare professional and employer/line-manager interviews will last up to 45 minutes, though this will vary depending on the individual circumstances of the interviewee.

Involvement in all aspects of the study will be actively promoted through the provision of Keele CTU contact details to provide extra information or assistance if required. Furthermore, reply prepaid return envelopes for the return of questionnaires will be used to make returning questionnaires easy, and reminder questionnaires will be used to encourage participation.

Each participating general practice will be provided with a site file containing details of the study, to ensure that practice staff know what will be asked of the patients within their care.

It is recognised that participants will face some burden with regards to the time to complete the questionnaires, engage with the vocational advice intervention and/or interviews for those who agree to take part in the qualitative study. However, all measures and methods included within this trial, have been selected on the basis of their reliability, validity, acceptability and appropriateness for use within this population.

All of the questionnaires and qualitative procedures have been previously used within similar population/patient samples. As outlined in section 8, up to 20 participants, and up to 20 VSWs, clinicians and employers will be invited to take part in the interviews in the internal pilot and main RCT. We feel the topics discussed with all groups will be unlikely to cause any distress, however it will be made clear at the start of each interview that participation is entirely voluntary and that participants are not obliged to answer specific questions if they feel they are not applicable or do not want to. All participants will be made aware within the information sheets that they are free to withdraw at any time, up to one month following the interview, without giving a reason, and that this study will not affect their current or future healthcare.

13.3. Regulatory compliance

The study will be conducted in accordance with the principles of Good Clinical Practice (GCP) in research studies and the UK Policy Framework for Health and Social Care Research. Keele University as the Sponsor has a quality management system in place containing SOPs which will be adhered to in the conduct of the trial. Studies supported by Keele CTU may be subject to an audit by Keele University as the Sponsor for quality assurance.

13.4. Protocol compliance

Non-compliance may be identified through any study activity but in particular through the use of central monitoring procedures such as consent form review or data management, and through self-reporting by the participants, and VSWs. Analysis of the VSW-patient consultation audio recordings may also identify protocol deviations. Deviations from protocols and GCP may occur in research studies. The majority of these instances are technical non-compliances that do not result in harm to the study participants, do not compromise data integrity, or significantly affect the scientific value of the reported results of the study. All deviations will be documented, and appropriate corrective and preventative actions will be taken by Keele CTU with responsibility being taken by the CI and where needed with agreement from the TSC.

13.5. Notification of serious breaches to GCP and/or the protocol

All staff involved in the study are required to notify the trial manager at Keele CTU and then the AI and CI immediately of a potential serious breach. A "serious breach" is a breach which is likely to affect to a significant degree:

- The safety or physical or mental integrity of the participants of the study; or
- The scientific value of the study.

In the event of doubt, or for further information or guidance, staff should contact Keele CTU.

13.6. Data protection and patient confidentiality

All information collected during the course of the trial will be kept strictly confidential. Information will be held securely and managed electronically by Keele University through Keele CTU. Keele CTU complies with all aspects of the General Data Protection Regulation (GDPR) 2018 and operationally this includes:

- consent from participants to record personal details including name, date of birth, address, sex, telephone number, email address
- appropriate storage, restricted access and disposal arrangements for participant personal and clinical details
- all CRFs that are transferred to and from Keele CTU will be coded with a study number and will include further participant identifiers, usually the participants' sex and date of birth
- where pseudonymisation of documentation is required, participating centres are responsible for ensuring only the instructed identifiers are present if the documentation is to be sent to Keele CTU. All research data will be anonymised as quickly as possible
- if a participant withdraws consent from further study participation including further collection of data, their data collected up to the point of withdrawal will remain on file and will be included in the final study analysis, unless requested otherwise.

All sensitive and personal electronic data will be housed in the CTU infrastructure, which is a secure virtual network requiring two factor authentication in order to access the data stored within. Roles and permissions are applied to users within the network as well as within an application to restrict what data a user can access and operations they can perform. Once data collection has been completed, all data will be maintained in such a form that they cannot be linked with identifiable participants and will be anonymised in the reports and for archival deposit. There are secure physical storage arrangements for the hard copies of consent forms and other hard copy documents

at Keele CTU within lockable filing cabinets. The building that houses Keele CTU operates a secure entry system to ensure only appropriate persons can enter the relevant areas of the building.

13.7. Indemnity

The trial is sponsored by Keele University and Keele University will be liable for negligent harm caused by the design or management of the study.

The NHS has a duty of care to patients treated, whether or not the patient is taking part in a research study, and the NHS organisation (general practices in this case) remains liable for clinical negligence and other negligent harm to patients under this duty of care.

As this is an investigator-led study, there are no arrangements for non-fault compensation.

13.8. Post study care

All participants in the trial will continue to receive usual care from their treating clinician(s). The study will not provide treatment or make recommendations regarding diagnosis or clinical treatment for individual participants either during the study or subsequent to study completion. Where participants have not achieved sustained RTW by 6 months, they will be directed towards state level support to manage their health and work and as such they will be signposted to the Jobcentre Plus for advice and if appropriate, on starting an application for Universal Credit.

13.9. Access to the final study dataset

Any subsequent requests for access to the data from anyone outside of the research team (e.g. collaboration, joint publication, data sharing requests from publishers, and legal representatives) will follow the Keele University's data sharing procedure. Keele University is a member of the UK Reproducibility Network and committed to the principles of the UK Concordat on Open Research Data. The School of Medicine and Keele Clinical Trials Unit have a longstanding commitment to sharing data from our studies to improve research reproducibility and to maximise benefits for patients, the wider public, and the health and care system.

14. Patient and Public Involvement and Engagement (PPIE)

Keele University's PPIE infrastructure includes a large Research User Group (RUG), which advises on our research projects throughout different stages. When developing the grant application and protocol for this study, dedicated meetings with patients who had experience of working with health conditions were organised, which involved our PPIE representatives. Their contributions have helped further shape the trial in the following ways:

- their experiences have influenced us to broaden the patient population for vocational advice in primary care (from musculoskeletal pain to the broader group of patients receiving a fit note for time off work from clinicians in general practices), and to focus on those patients who have had a fit note for two weeks or more (rather than those with shorter work absences)
- shaped plans for patient recruitment and participant eligibility criteria
- the trial includes some brief but regular data collection by SMS text messaging; PPIE members have shaped the plans for the frequency and wording of these texts
- recommendations around the participant information sheet (PIS) to ensure it makes the valuable contribution to the research clear, particularly for those in the control arm of the trial
- suggested that delivery of vocational advice should be mostly by phone, supported where desirable and available by other technology (e.g. videoconferencing such as Skype) to provide face-to-face contact, as well as the option for in-person face-to-face consultations as part of step 2 of the stepped care vocational advice intervention
- PPIE members expressed their desire to continue their involvement with one joining the research team as a co-applicant a broader PPIE group to provide ongoing support to the TMG and the TSC.

As part of the feasibility study PPIE members will be involved in the adaptation of the intervention and will continue to provide support at regular intervals throughout the research programme. This will include supporting the development of all patients facing materials, and advising on processes of recruitment and delivery of the intervention. PPIE members will also support the dissemination plans ensuring that there is sufficient and appropriate dissemination to patients and the public.

15. Dissemination

Our main findings on the effectiveness and cost-effectiveness of vocational advice in addition to usual primary care will have important implications for patients, the NHS and policy. To ensure that the outputs from the research inform policy and practice and benefit patients, the following dissemination strategy has been developed based on the NIHR "Push the Pace" guidance, draws on our extensive existing communication channels and networks and engages with Keele University's Impact Accelerator Unit.

Findings of this trial will be presented at local, national and international conferences and published in peer reviewed journals. All journal articles based on WAVE data will be free to

access. Once the results have been published further dissemination to the wider public will be carried out via updates on Keele University's website, as well as contact with the participating general practices (e.g. summary results for participating practices websites), and summary results passed on to any related patient groups aligned to those participating practices. Study participants will be informed about the study progress for example via newsletters or posters in the participating practices and through Keele University's website.

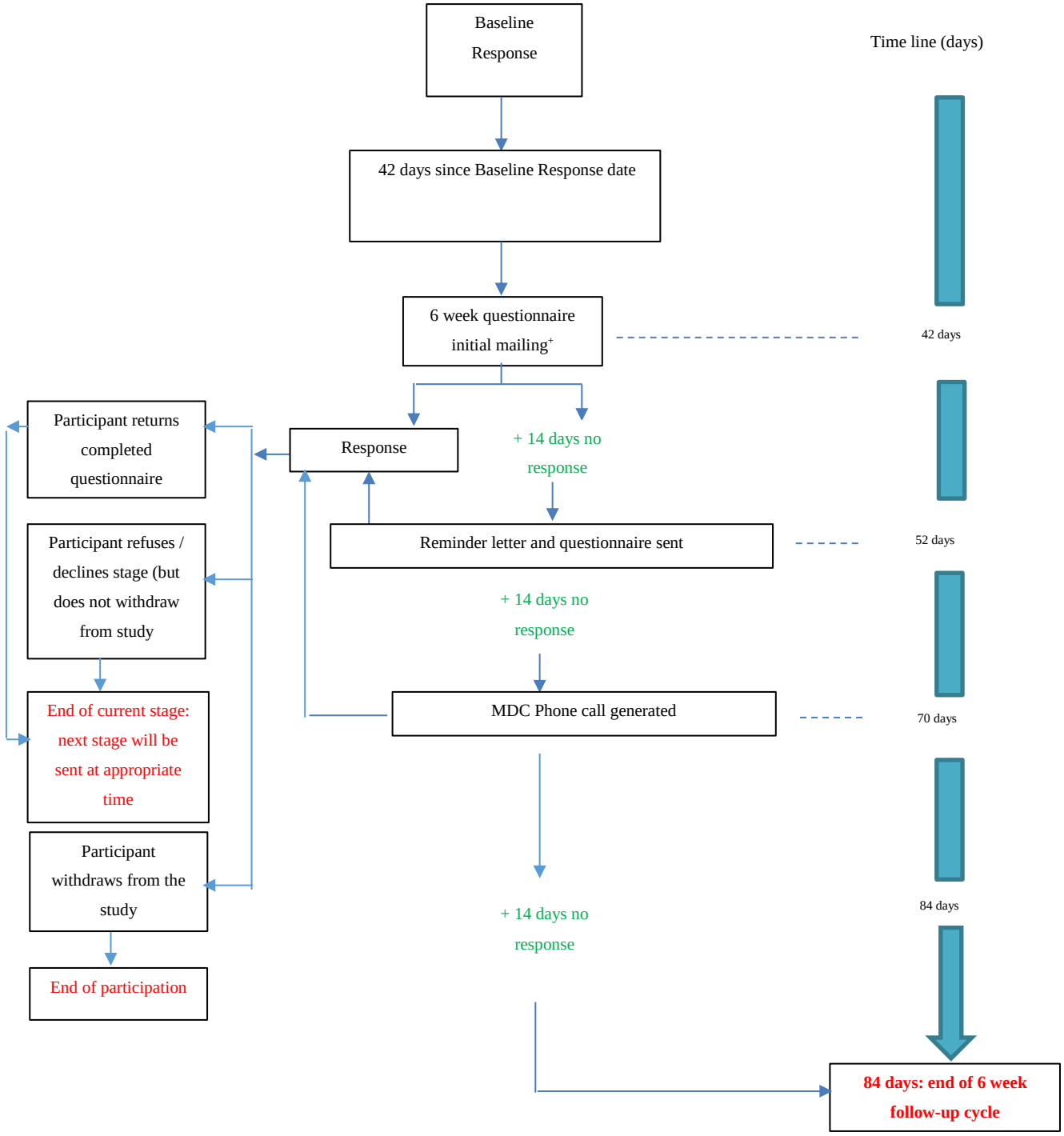
As described in section 14 our PPIE will contribute to dissemination of study findings by: helping to interpret study findings from a patient perspective; advising on how best to publicise the study findings to the wider public; supporting the design of evidence-based information materials (sheets, online tools, patient stories) regarding managing health and work.

16. Potential impact of COVID-19 on WAVE

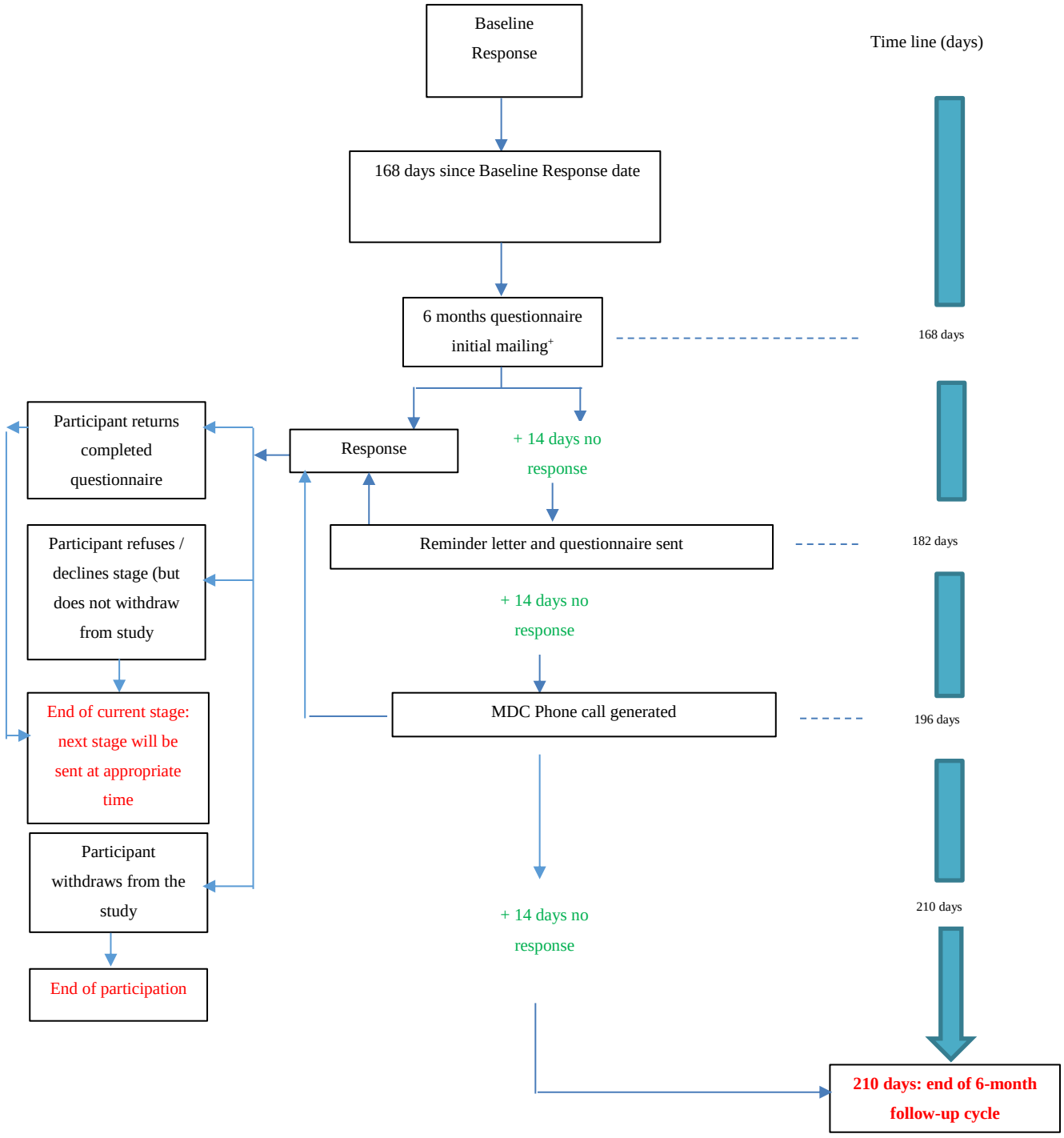
The WAVE trial focuses on supporting patients in primary care who receive a fit-note to take fewer days off work due to health conditions. The impacts of COVID-19 on the working environment are likely to be long-term and the research team has ensured that the intervention and associated training take these impacts into consideration. Recruitment will take place remotely and can be carried out whether the participants contact their healthcare team in person or via phone or video conference. The intervention is planned to be delivered remotely, by phone and video conference, with optional face to face consultations with the VSWs and workplace visits only where it is deemed necessary and is safe to do so. At baseline the participants email address is collected as part of the consent form, this will allow electronic questionnaires to be sent to participants should another period of lockdown mean that follow-up postal questionnaires cannot be processed within Keele CTU. The interviews included as part of the feasibility and trial evaluation may also be undertaken by phone or video conference if a face to face meeting is not possible. These measures ensure that the safety of participants, VSWs and the research team can be maintained in the changing environment. They also ensure that the trial can continue whilst taking into account the possibility of a changing impact of COVID-19 on health services and workplaces.

Appendix 1: Follow-up flow diagrams

WAVE follow-up flow diagram: 6 weeks (feasibility and main RCT)



WAVE follow-up flow diagram: 6 months (main RCT)



If no response at a specific stage (and not withdrawn from the study), then participant will remain in study for next follow-up stage

*to participants who provided consent to follow-up at baseline and who have not subsequently withdrawn

+ Includes initial letter of invitation and Questionnaire

Appendix 2: Intervention development team

The intervention team includes: Sowden, Consultant physiotherapist with expertise in the design of training to deliver complex interventions including vocational advice; Madan, occupational health physician with expertise in the design and delivery of occupational health training to support patients with MH conditions and clinical experience of delivering occupational health services; Chew-Graham, academic GP with expertise in managing mental health conditions and health and work in primary care, and expertise in designing and delivering training interventions in mental health trials in primary care; Walker-Bone, Rheumatologist with expertise in managing musculoskeletal conditions and expertise in designing and delivering training interventions for vocational advice; Mansell, Lecturer in Health Psychology with expertise in behaviour change theory and mediation analysis; Wynne-Jones, Reader with expertise in designing and delivering training interventions for vocational advice, and trials methodology.

Appendix 3: Risk protocol

General statement

The participant's General Practitioner (GP) is responsible for the ongoing clinical care of participants. This protocol covers risk associated with ideas of self-harm and/or suicide expressed by WAVE study participants.

WAVE Vocational Support Workers (VSWs) will be delivering the WAVE trial intervention and WAVE researchers will be conducting qualitative interviews, as part of the WAVE trial. The Risk of Self-harm and/or Suicide Protocol must be initiated by the VSWs or WAVE researchers if a WAVE study participant discloses thoughts of self-harm or suicide.

The WAVE researchers have a duty of care to ensure that the GP is notified if a WAVE study participant expresses thoughts of self-harm or suicide.

At the beginning of the interview (in the qualitative study) or during the interaction with the VSW (in the trial) the name of the participant's GP and telephone number will be obtained, and the researcher will explain to the study participant why this is needed.

The WAVE study participant should be advised that any concerns over specific medical symptoms should be discussed with their primary care team.

Definition of suicide ideation:

Study participants who disclose information during an interview with the WAVE researcher or VSW, or to a member of the research team indicating that they have attempted suicide or that they have been thinking of ways to end their own life will be considered to have suicidal ideation.

Definition of Self-harm:

Self-harm is defined as an intentional act of self-poisoning or self-injury irrespective of the motivation (RCPsych, 2010). Self-harm intent is defined as any expression from the study participant to the researcher/VSW stating (s)he is planning to self-harm.

Action required

A schematic of the risk of self-harm or suicide ideation pro forma is shown in figure 1.

1. **Before each contact with a WAVE participant** (either telephone or face-to-face), a WAVE researcher or VSW should review any available information on self-harm or suicide ideation and ensure that contact details for the nominated clinician with clinical responsibility (or nominated deputy) are current.

2. If a WAVE researcher or VSW becomes aware that a participant has thoughts of self-harm or suicide, they should first ascertain whether the participant has talked to his/her GP about them. The WAVE researcher should reinforce the importance of starting or maintaining a

dialogue with his/her GP and ask for permission to communicate the thoughts of self-harm or suicide to his/her GP. Suggested scripts for this are shown below.

a) If the participant agrees to this communication, the WAVE researcher or VSW should telephone the participant's GP within 48 hours** to pass on the information obtained. If the participant's named GP is not available, then the WAVE researcher should ask to speak to the duty doctor. The WAVE researcher should make it clear to the GP that a risk assessment has not been performed, and that clinical responsibility for the participant remains with GP. A **notification of self-harm or suicide ideation letter** should be completed and emailed to the GP.

b) If the participant does not agree to their GP being informed, the WAVE researcher or VSW should contact the Nominated clinician l or his/her nominated deputy to discuss the participant. The nominated clinician will examine the participant's data and if appropriate, will assess the participant by telephone. If the nominated clinician considers the participant to be at risk of attempting suicide, the participant's GP will be notified **with or without** the participant's consent. However, the nominated clinician or deputy may contact the GP (with or without the study participant's consent) without first assessing the participant her/himself if in their clinical opinion, the situation is urgent. In these cases, the decision should be explained to the participant as soon as possible.

3. The WAVE researcher should inform the Chief Investigator by completing a disclosure report and passing this to him/her for approval. The Nominated clinician will review the disclosure report and decide if the WAVE participant is at significant risk and take appropriate action, i.e. withdraw the participant from the study and contact their GP.

**If the WAVE researcher believes the participant is in immediate danger, they must immediately contact the Nominated clinician for the WAVE trial, who will take appropriate action.

Suggested Scripts:

Disclosure

I am concerned about some of the things you have told me. Have you spoken to your doctor (GP) about them? It is important that your GP knows about the way you feel, as they will be able to make sure that you have the necessary support in place. Are you happy for me to mention to your GP the things you have told me?

If the participant is hesitant or declines

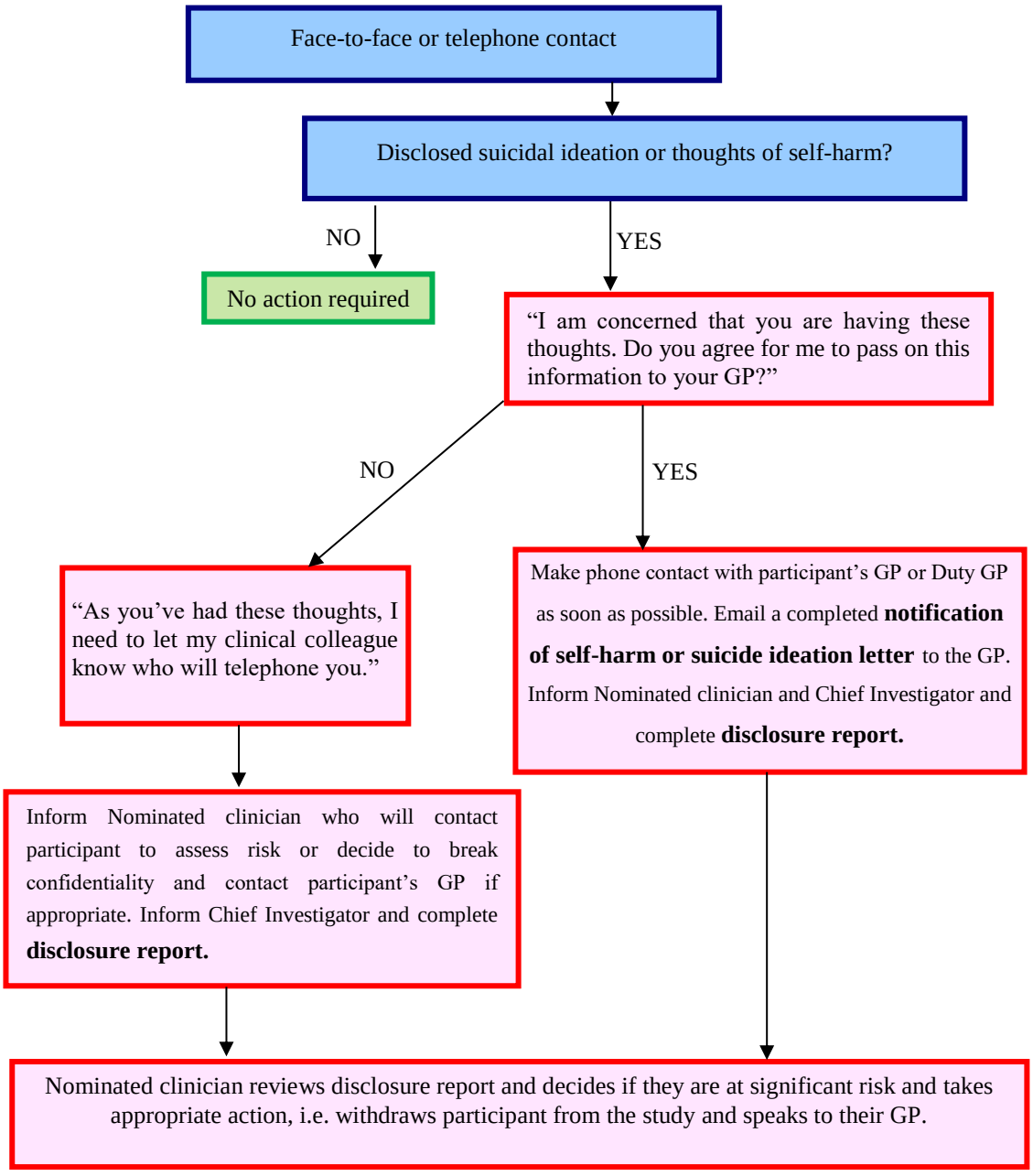
Many people find it hard to bring these things up during a consultation, but your GP can offer you help with these feelings. If he/she knows how you are feeling, he/she will be able to talk to you about it and together you can decide on the best way to treat you.

If the participant continues to decline

That's fine, but as I am not a doctor, I do have to let my medical colleague in the WAVE study know about the way you are feeling. (S)he may phone you today or in the next day or so to have a talk to you about the way you are feeling. (S)he may need to speak with your GP.

Figure 1 – Suicide ideation pro-forma

The following action must be taken and recorded by a member of the VSW or wider research team whenever a participant discloses suicide ideation to a VSW or researcher.



Nominated members of study team:

Nominated clinicians:

(1) Keele University: Prof Carolyn Chew-Graham, Tel: 07425 620228

(2) Guy's and St Thomas' NHS Foundation Trust: Dr Ira Madan, Tel: 07791 599272

(3) Southampton General Hospital: Prof Karen Walker- Bone, Tel:07967 152844

Chief Investigator: Keele University: Dr Gwenllian Wynne-Jones, Tel: 01782 733962.

GP name
Address line 1
Address line 2
Address line 3
Post code

Date: [Date]
Our ref: [Study ID]

Dear Doctor,

Work And Vocational advicE (WAVE) study
Notification of self- harm or suicide ideation

Patient's Name: [patient name] **DOB:** [patient's date of birth]

The above patient is taking part in our study exploring whether a brief vocational support intervention delivered in primary care can reduce sickness absence among employees consulting in general practice and receiving a fit note. I am writing to notify you that the above patient reported thoughts of self-harm or suicide to me during our conversation <<***time period***>> today.

The patient disclosed the following information during an interview with a Vocational Support Worker / WAVE researcher <add further detail>

We would respectfully remind you that a risk assessment has not been carried out as part of the study, and on-going clinical care remains with you. It is part of our study protocol to inform you of such risks, so that you can take account of them in your management of this patient.

Yours sincerely,

[insert signature]

[insert name]
on behalf of the WAVE study team

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DISCLOSURE REPORT

PARTICIPANT NAME: _____ DOB: _____ ADDRESS _____ PHONE NUMBER(S): _____

GP PRACTICE: _____

Time point	Date	Risk Identified	Researcher	GP Informed	Name of GP	Date GP Informed	Brief summary of information given to GP	Risk Identified[3]	Signature of clinician
Interview or VSW contact (face-to-face/telephone)		Yes/No		Yes/No				Yes/No	

[3] **As per the protocol, those at risk of self-harm/ suicide will be assessed by a Nominated clinician, who will use their clinical judgement to decide if the participant is at significant risk and needs to be withdrawn.**

Please enter other relevant information overleaf

(1) Keele University: Prof Carolyn Chew-Graham, Tel: 07425 620228

(2) Guy's and St Thomas' NHS Foundation Trust: Dr Ira Madan, Tel: 07791 599272

(3) Southampton General Hospital: Prof Karen Walker- Bone, Tel:07967 152844

Chief Investigator: Keele University: Dr Gwenllian Wynne-Jones, Tel: 01782 733962.

Other relevant information:

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