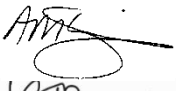




Work And Vocational advice (WAVE) in primary care: a randomised controlled trial Data Analysis Plan for the Feasibility Phase

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IRAS Number: 279481

Clinical Trials.gov: NCT04543097

Sponsor Number: RG-0283-19

Funders Number: NIHR Health Technology Assessment (17/94/49)

Draft number: Version 1.0 Date: 30/09/2021

Declaration regarding undertaking of the analysis

Kieran Bromley (study statistician) will be undertaking data cleaning and analysis of the study data under the guidance and supervision of the Dr Martyn Lewis (senior statistician). Analysis of the main progression criteria outlined in Section 7 will be performed independently by the senior statistician to ensure the integrity of the findings.

With reference to Protocol version: 3.0 (Date: 18/03/2021)

Authorisations (where applicable)

Approved by	Designation	Signature & Date
.....	TSC chair (after seeking approval from the other TSC members)	
.....	DMC chair (after seeking approval from the other DMC members)	

Version History Log

Version	Date implemented	Section no. changed	Details of changes with justification
1.0	dd/mm/yyyy		

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1. Background and aims

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.

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. 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.

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 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. The WAVE study is split into a number of phases including a feasibility study and parallel-group randomised controlled trial (RCT) with internal pilot phase.

The specific objectives in this DAP relate to the feasibility phase of the WAVE study (section 2.1.1 of the Protocol version 3.0) and more specifically objectives (iv) quantitative and (v) qualitative as noted in the protocol; hence:

Quantitative objective: 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.

Qualitative objective: 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. 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 the recruitment methods, patients' willingness to engage with the intervention and intervention fidelity, including linked qualitative interviews with participants. A single group (intervention group) feasibility study will be undertaken in three centres [Keele (West Midlands), London and Southampton n=30 (aiming for 10 participants from each centre)]. GP Practices will use one of three recruitment methods (A, B, or C – as shown in Appendix A) for identifying and recruiting patients into the feasibility trial. The steps of the intervention are described in detail in Section 3.5.2 of the protocol (version 3.0). 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) and minimal data collection procedures (see Appendix B for a flow diagram highlighting the data collection process).

3. Study and evaluative population

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 Duijn *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.

Appendix A shows a study flowchart which will highlight the following key points within the study:

- Method A:
 - Number of pop-ups fired in the GP consultation (when the patient is present).
 - Number of patients who provide consent to share their contact details with the study team.
 - Number of patients who return a study pack which was sent from Keele CTU and are confirmed to be eligible.
- Method B:
 - Number of pop-ups fired in the GP consultation (when the patient is not present).
 - Number of patients confirmed as eligible by the GP.
 - Number of participants who are sent a study pack from the practice.
- Method C:
 - Number of patients that are issued with a fit note.
 - Number of patients, who have not previously been screened or invited, that are tagged as potentially eligible.
 - Number of patients who are confirmed as eligible by practice and sent a study pack from the practice.
- Methods A, B, and C:
 - Number of participants consenting to take part in the study.
 - Number of participants who have at least one contact with the vocational advisor (as per feasibility progression criteria (ii)).
 - Number of participants returning completed 6-week study data (both via mailed questionnaire and minimal data collection (MDC)).
 - Completeness of SMS returns over the 6-week follow-up period.

For a full description of the different methods of identifying participants from the GP practices, please refer to Sections 4.3.1 - 4.3.3 of the study protocol (version 3.0).

4. Outcomes

As per CONSORT-extension for pilot and feasibility trials (Eldridge et al, 2016) the main objectives and outcomes for a pilot and feasibility trial should be focused on feasibility and process outcomes. Further, it is recommended that key process outcomes should encompass progression criteria for informing decision next steps for the WAVE programme. Whilst process outcomes are the main outcomes of the feasibility phase data will also be collected on clinical outcomes assessed through self-report questionnaires and qualitative data on patient and health professional interview assessment.

Process outcomes

To assist decision making about whether to proceed to the next phase (the internal pilot RCT), the main stop/amend/go criteria in the feasibility phase are:

- i) Recruitment uptake: an uptake of <25% of those eligible and expressing an interest in the study (red), 25%-49% (amber), and $\geq 50\%$ (green).
- ii) Intervention fidelity: the percent of patients who have at least one contact with a vocational advisor (VA) <40% (red), 40%-65% (amber), and >65% (green).

Other key feasibility measures are:

- Number of patients who are identified by the pop-ups, in each method of identification.
- Number (percent) of patients who are eligible and interested by method (as described in Section 7 – Method of analysis).
- Number (percent) of patients who consent to participate by method.
- Number (percent) of study participants who engage with each step of the study intervention.

Assessment of fidelity will also be based on the content of the consultations which study participants have with the VSWs, through recording phone calls/face to face/video meetings with the VSW and examining Case Report Forms (CRFs) completed by the VSW detailing the content of the intervention delivered.

Self-report patient questionnaires

To collect baseline and outcome data, participants will be sent postal questionnaires shortly after the consultation where they receive a fit note, and at 6 weeks. The baseline questionnaire will include the main trial primary and secondary outcomes, key anticipated mediators, health economic variables and demographic information. The questionnaire at 6 weeks will include the primary outcome to be used in the main trial (and internal pilot phase) and key anticipated mediator variables only (see Appendix C) for the 6-week data collection process. The primary outcome measure of work absence will be assessed by asking participants to report how much time off work they have had due to their health condition, specifically: “How much time off work during the past 6 weeks 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 weeks (Days).” Included patient questionnaire items/scales for baseline and 6 weeks (including minimal data collection (MDC) stage) are presented in Appendix C.

Participants will be asked fortnightly whether they have returned to work, for a period of 6 weeks in the feasibility phase or until a sustained ‘return to work’ (RTW) is achieved (defined as return to *any work* for at least 4 weeks). RTW and general health 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.

5. Sample size

In this feasibility stage, the target sample size is $n=30$ where all participants receive the planned intervention, with the aim of 10 participants being recruited from each of the three centres (Keele – West Midlands, London, and Southampton). There is no randomisation procedure implemented at this stage of the study. The sample size of 30 participants in the intervention arm for this feasibility phase aligns closely with the typical size per arm for pilot/feasibility trials (Billingham et al, 2016).

6. Participant (baseline) characteristics

Appendix (F) shows the characteristics which are measured at baseline for recruited participants. This includes number of days absence, work interference (WPAI), physical and mental health (SF12), depression (PHQ 8), anxiety (GAD 7), attitudes and beliefs towards work, return to work self-efficacy, physical activity, use/content with other services providing vocational advice and detailed information about current work (current job title, type of work, including working hours, work and workplace characteristics, salary, satisfaction, and commuting).

No statistical hypothesis will be carried out on the descriptive information recorded at baseline; this data will be presented descriptively using the appropriate summary measure for each variable (mean (SD) for continuous normally distributed variables, median (IQR) for non-normal data, and frequency counts (%) for categorical data). Descriptive summaries will be presented overall. A summary split by method of recruitment will also be scrutinised to check any potential imbalance in characteristics of patients recruited according to the two methods.

7. Method of analysis

The feasibility trial progression criteria are as follows:

- i) Recruitment uptake: an uptake of <25% of those eligible and expressing an interest in the study (red - stop), 25%-49% (amber - amend), and $\geq 50\%$ (green - go).
- ii) Intervention fidelity: the percent of patients who have at least one contact with a vocational advisor (VA) <40% (red - stop), 40%-65% (amber - amend), and >65% (green - go).

For feasibility outcome i), those who are eligible and interested (the denominator figure) will be determined as the group of patients who are screened as potentially eligible by the site (according to the inclusion/exclusion criteria from the site assessment), with interest in taking part in the study confirmed by returning their study pack containing either or both a full/partially completed baseline questionnaire and/or consent form. The numerator (denoting study participation) will then be patients who are originally screened as potentially eligible by the site and return their study pack but more exclusively, return a fully complete consent form and confirm they have not yet returned to work by responding 'YES' to question A1 ("Are you still absent from work as a result of your health condition?") in the baseline questionnaire. The proportion of uptake will be presented both split by method, and an overall total. The overall total will be summed across all three methods of patient identification and will be used to assess progression.

For feasibility outcome ii), patients who have contact with a vocational advisor will have a date of initial contact recorded within the WAVE Assessment and Action Plan (WAAP) form. The total denominator is the number recruited (anticipated n=30) and the numerator will be the number of participants who have at least one contact (via face-to-face/videoconferencing, telephone) with the VA. These feasibility outcomes will be used to determine, in collaboration with the Trial Steering Committee and Data Monitoring Committee, whether to proceed to the RCT phase using the traffic-light system for each of the two feasibility criteria as guidance.

Analysis of the single group feasibility study will report the numbers and proportions of potentially eligible patients identified (by all methods of patient identification – see Appendix D), 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 (as described in Section 3.5.2 of the protocol, version 3.0) 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) (see Appendix E).

The flow of patients through the study will be presented in a flowchart (see Appendix A). Reasons for patients not being eligible and not wishing to consent to the study will also be summarised (as available) for comparison with those eligible/consenting. Graphical representations of participant identification and recruitment will be produced, showing both the cumulative numbers of patients identified and recruited on a week-by-week basis, with additional information showing the counts of patients identified by both Method A, Method B, and Method C. Age and gender will be compared between patients who did and did not provide consent.

Return rates and responsiveness to mailing questionnaires will be assessed (6 months returns in total and split according to mailing and MDC response), by presenting numbers (%) of questionnaires which are returned and assessing the rate of completion of the primary and key secondary outcomes in the baseline and 6-week questionnaire. Data collected from the baseline and 6-week questionnaires will be presented by site and overall (see Appendix F and G). Fortnightly response rates to SMS messages will be calculated for each SMS message sent (overall and split by follow up time interval of 2, 4 and 6 weeks); counts per person will also be evaluated and the number (percent) of 0, 1, 2, 3 responses will be presented (see Appendix H). As for baseline, descriptive summaries of the (questionnaire/SMS) data at follow-up will be presented using mean/median and SD/IQR for numerical scales (according to data distribution) and number (percent) for categorical responses. Participant demographics and key baseline variables (such as main health condition causing time off work and working hours) will be assessed by method of recruitment (A, B and C) to ascertain whether there is any differential selection of patients between all methods. Response rates to SMS and the 6-week questionnaire will also be reviewed by all methods of identification (A, B and C).

Final analyses will be carried out once data collection, entering, and cleaning is complete. Data entry and cleaning will be undertaken in accordance with Keele CTU Standard Operating Procedures (SOP). The statistical programmes SPSS (version 24 (or higher)) and R (version 4.0.3 (or higher)) will be used to carry out the required statistical programming and analysis.

8. Health economic methods

Not applicable to the feasibility phase (healthcare resource use questions are not collected in the feasibility phase but will be included in the main RCT phase).

9. Qualitative methods

All patient 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.

Additionally, up to ~10 recorded phone calls and face to face/ video consultations between VSWs and patients will be transcribed and analysed using techniques of discourse analysis [Roberts and Sarangi, 2005] to investigate of how the different components of the VSW intervention are delivered in consultations.

10. References

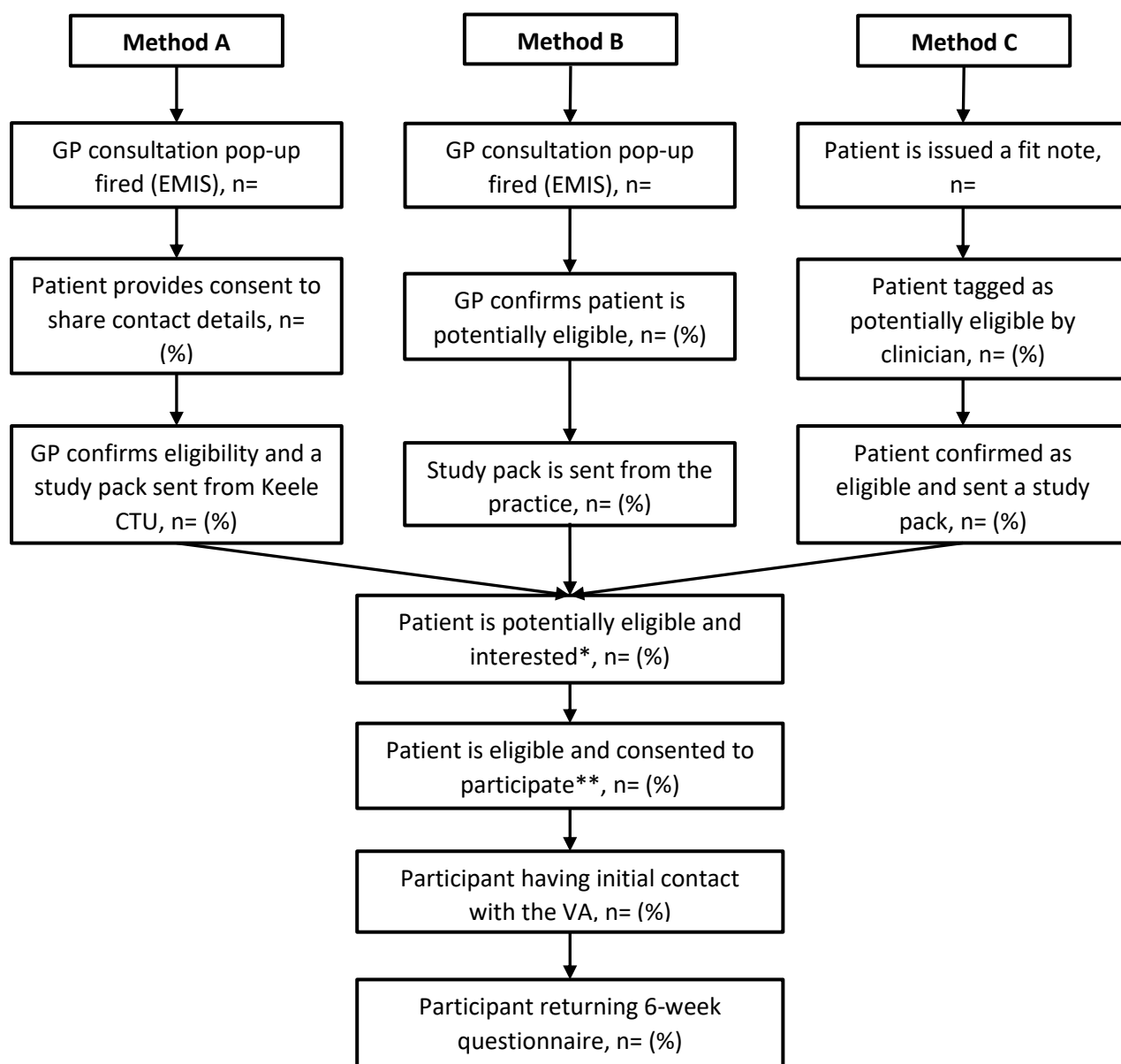
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11. Appendices

A. Study flowchart

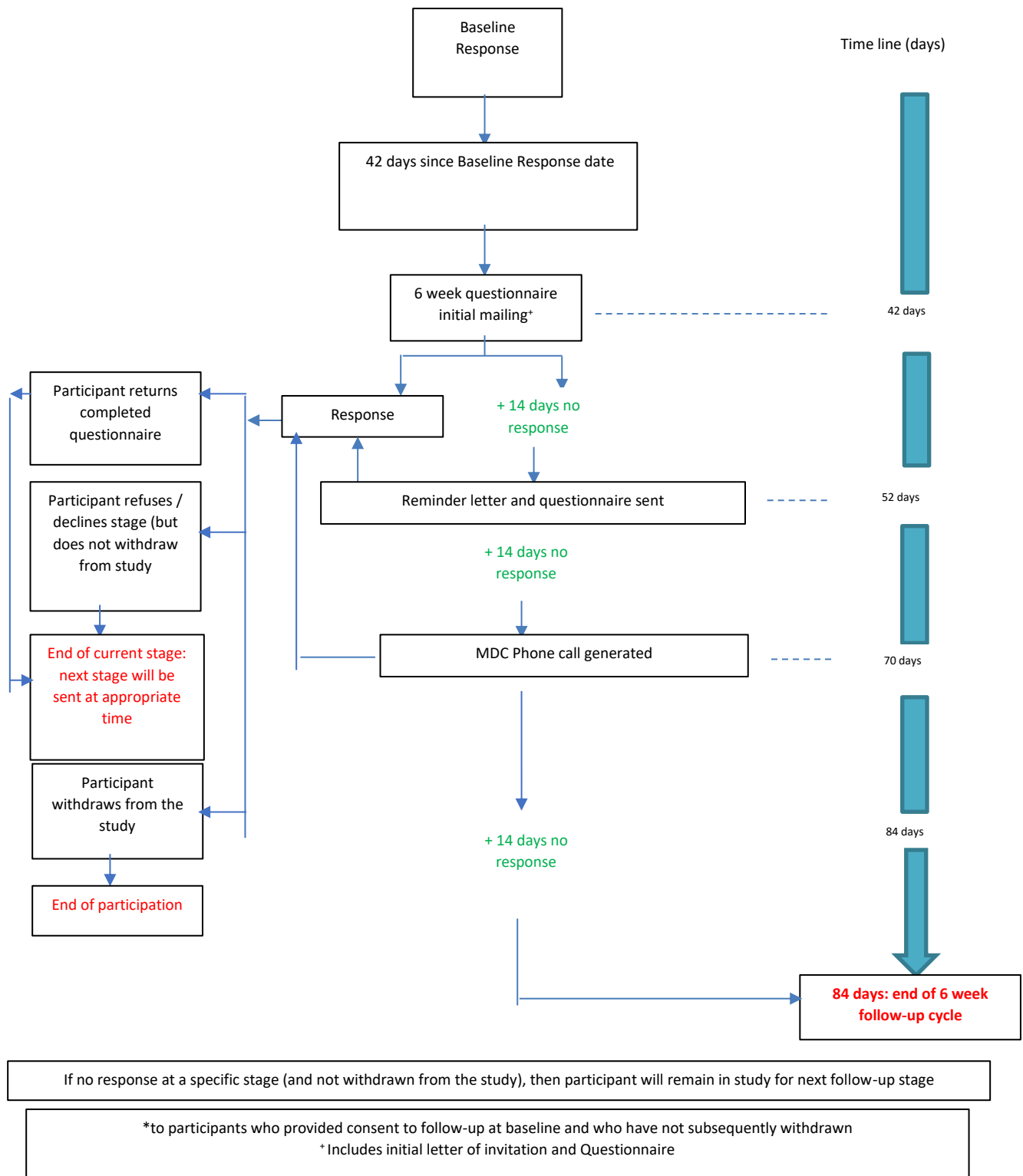


* The patient has returned their study pack containing their consent form and/or questionnaire. *Potentially eligible refers to the patient being determined as potentially eligible to take part in the study according to the site criteria (i.e., fulfilling all inclusion/exclusion criteria at study site assessment). Interested is defined as returned full/partial completion of either or both the baseline questionnaire and/or consent form.*

** The patient has confirmed in their questionnaire that they are eligible as they have not yet returned to work ('yes' response to question A1 confirming that the patient is still away from work) and provided full consent to participate in the study.

Method A, B and C of patient identification are explained in detail in the protocol (Section 4.3.1 - 4.3.3, version 3.0). In brief, method A is identification through an automated health informatics IT protocol during 'real-time' consultation; method B is identification through back dated searches of the general practice medical record after the consultation; method C is a back dated search through GP medical records to identify potentially eligible patients.

B. WAVE follow-up flow diagram: 6 weeks



C. Table of patient characteristics collected at baseline and follow-up:

Description	Measure	Baseline Q	6-week Q	6-week MDC	Additional information about the scale
<i>Number of days absence</i>	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	✓	✓	✓	
<i>Time taken to RTW</i>	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	
<i>Work interference</i>	Work Productivity Activity Impairment (WPAI) questionnaire	✓	✓	x	Min= 0% (No impairment/Very high productivity), Max= 100% (Greatest impairment/very low productivity). Items 1-3 ask about hours not worked due to health problem, other reasons, and hours worked. Items 4-5 ask about the degree that health problem affects productivity and normal activities, scored as 0-10. Information on scoring at: http://www.reillyassociates.net/WPAI_Scoring.html [WPAI:GH]
<i>Work performance</i>	Single item question (SIPQ) from the WPAI, asking participants' to what extent their health condition has impacted on their performance at work	✓	✓	x	Min= 0 (Health has not affected work performance), Max= 10 (Health problems are so bad I am unable to do my job). Single item questionnaire.
<i>Physical health</i>	Short Form 12 (SF12)	✓	✓	x	Min= 0 (Worst physical health score), Max= 100 (best physical health score). SF-12 version 2 scoring algorithm available.
<i>Mental health</i>	Short Form 12 (SF12)	✓	✓	x	Min= 0 (Worst mental health score), Max= 100 (best mental

					health score). SF-12 version 2 scoring algorithm available.
<i>Depression</i>	Patient Health Questionnaire (PHQ) 8	✓	✓	x	Min= 0 (No depression), Max= 24 (Severe depression). Total score is the sum of all items (8 items, with item responses of 'not at all', 'several days', 'more than half the days' and 'nearly every day'.
<i>Anxiety</i>	Generalised Anxiety Disorder (GAD) 7	✓	✓	x	Min= 0 (No anxiety), Max= 21 (Severe anxiety). Total score is the sum of all items (7 items, with item responses of 'not at all', 'several days', 'more than half the days' and 'nearly every day'.
<i>Attitudes and beliefs to work questionnaire</i>	Recently developed measure, to examine the impact of attitudes and beliefs to working on patient outcomes	✓	✓	x	Min= 0 (Not impacting return to work), Max= 60 (high impact on returning to work). Total score is a sum across all items (10 items scored 0-6, where 0=strongly disagree and 6=strongly agree).
<i>Return to work self-efficacy</i>	Return to work self-efficacy (RTW-SE) [50]	✓	✓	x	Min= 1 (low self-efficacy), Max= 10 (high self-efficacy). Score is taken as the mean of all 19 items (19 items scored 1-10, where 1=not at all confident and 10=totally confident).
<i>Physical activity level</i>	General practice physical activity questionnaire (GPPAQ3)	✓	✓	x	Participants are scored as either 'inactive', 'moderately inactive', 'moderately active' or 'active'. Scoring information, algorithm and tool can be found at: https://www.gov.uk/government/publications/general-practice-physical-activity-questionnaire-gppaq [Guidance document, page 13]
<i>Use and content of other services providing vocational advice</i>	Single question: Have you seen any of the following to talk about issues at work in relation to your current health condition(s)?	✓	✓	x	Response options are: Vocational advisor; GP, My company's occupational health department; Practice nurse; Physiotherapist; Other (with option to specify).
<i>Current job title</i>	Free text used to allocate socioeconomic status	✓	x	x	Free text response.
<i>Type of work</i>	Two questions: What does the firm/organisation you work for mainly make/do?	✓	x	x	Free text responses.

	What do you mainly do in your job?				
<i>Work role returned to</i>	If you have returned to work are you currently:	x	✓	x	Response options are: Doing your usual job; On paid leave/annual leave; Working fewer hours; Doing lighter duties; On paid sick leave; Unpaid sick leave
<i>Working hours</i>	Are you working full time ≥ 35 hours per week or part time <35 hours per week	✓	✓	x	
<i>Working hours</i>	Please write the total number of hours you are paid to work each week	✓	✓	x	Numeric cell to enter number of hours paid to work.
<i>Work characteristics</i>	Physical workplace demands, demand-control-support in the workplace	✓	✓	x	5 responses, where 1=Very good, 2= Good, 3= Not a problem, 4= Slight problem, 5= Major problem
<i>Workplace characteristics</i>	How many people are employed at your place of work?	✓	x	x	5 responses, where 1=Very good, 2= Good, 3= Not a problem, 4= Slight problem, 5= Major problem
<i>Salary</i>	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	£0-£99 (£0-£5,199 per year), £100-£149 (£5,200-£7,799 per year), £150-£249 (£7,800-£12,999 per year), £250-£349 (£13,000-£18,199 per year), £350-£449 (£18,200-£23,399 per year), £450-£599 (£23,400-£31,199 per year), £500-£749 (£31,200-£38,999 per year), £750 or more (£39,00 or more per year), Prefer not to say
<i>Satisfaction with work</i>	If you take into consideration your work routines, management, salary, promotion possibilities and co-workers, how satisfied are you with your work?	✓	✓	x	Single item, scored 0-10, where 0= not at all satisfied and 10= Completely satisfied.
<i>Commuting</i>	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	1= Walk, 2= Cycle, 3= Public transport, 4= Car (private or shared), 5= NA. Length of commute are free numeric cells for hours and minutes.
<i>Health related quality of life</i>	EQ-5D-5L	✓	✓	x	Min= -0.59 (Worst health utility), Max= 1.00 (Best health utility).

					Scores calculated via the Crosswalk method. Scale contains 5 items.
<i>Healthcare resource use</i>	Self-reported use of other healthcare services	✓	x	x	
<i>Fit note duration</i>	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	
<i>Health condition</i>	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	1= Aches and Pains, 2= Mental Health problem, 3= Other Health Condition. Participant should have responded 1=Yes to still being absent from work.
<i>Chronic health conditions</i>	List of 19 conditions participants to select those that apply to them	✓	x	x	List of response options can be found in Section H of the baseline questionnaire.
<i>Perceived change in the health condition for which the fit note was issued</i>	Single item with 6 response options completely recovered, much improved, somewhat improved, the same, somewhat worse, or much worse.	x	✓	✓	
<i>Age</i>	Self-reported date of birth	✓	✓	✓	
<i>Sex</i>	Self-reported sex, response options of female, male, prefer not to say	✓	✓	✓	0= Male, 1= Female, 3= Other
<i>Level of education</i>	Indication of highest level of education from GCSE to post-graduate / professional qualifications	✓	x	x	Participant can select multiple options of: o-Level/GCSEs, A-Levels, Vocational training certificates, and higher professional qualifications.

D. Audit tables from GP practices

Outcome	Keele (n=)	London (n=)	Southampton (n=)	Total (n=)
Method A identification				
Method B identification				
Method C identification				
Eligible - Not mailed by practice				
GP screened - not eligible				
Escaped without using				
No time				
Not appropriate				
Patient not present				
2nd screen not eligible				
Patient declined address share				
Keele - Wolstanton Medical Centre; London - Tessa Jowell GP Surgery; Southampton - Park Surgery Method A: patient identified as eligible and mailed from Keele CTU ; Method B: patient identified as eligible and mailed from the practice; Method C: back dated search of GP medical records and mailed from the practice.				

E. CRF01 – WAVE Assessment and Action Plan (WAAP)

WAVE Assessment and Action Plan (WAAP)	Keele (n=)	London (n=)	Southampton (n=)	Total (n=)
<i>Participant contacts</i>				
Total contact made, n (%)				
Phone calls				
Emails sent				
Video calls				
In-person meetings				
Participant was offered but unable to join video calls, n (%)				
In-person meeting offered but not possible due to COVID-19, n (%)				
<i>Healthcare Professional contacts (HCP)</i>				
Phone calls with HCP, n (%)				
Wrote to/emailed participant's HCP, n (%)				
<i>Employer contacts</i>				
Total contact made, n (%)				
Phone calls with participant's employer				
Video calls with participant's employer				
In-person meetings with participant's employer				
In-person meeting offered but not possible due to COVID-19, n (%)				
Wrote to/emailed participant's employer, n (%)				
<i>Consultation recordings</i>				
First session recorded and verbal consent obtained, n (%)				
Subsequent session recorded and verbal consent obtained, n (%)				
<i>VSW action taken</i>				
Explored participants current health/work situation, identifying obstacles in returning to work, n (%)				
Provided evidence-based reassurance regarding work and health relationship, n (%)				
Encouraged participants to make contact with their workplace, n (%)				
Discussed problem-solving of perceived obstacles to RTW with participant, n (%)				
Provided information and advice about sleep, n (%)				
Used the techniques of goal setting, n (%)				
Used the techniques of behavioural activation, n (%)				
Used the techniques of action planning, n (%)				
Discussed participant's RTW plan(s), n (%)				
Signposted to leaflets/resources/other services, n (%)				

Level of intervention delivered, n (%)

Step 1

Step 2

Step 3

Reason for ending VS

Participant has achieved 4 weeks sustained RTW, n (%)

Participant has decided to terminate employment, n (%)

Employers have terminated the participant's employment, n (%)

Absent from work for 6 months - signposting advice provided, n (%)

Absent from work for 6 months - signposting advice not provided, n (%)

Participant no longer wants contact/input from VSW, n (%)

Participant has withdrawn/been withdrawn from the study, n (%)

VSW cannot help with the obstacles to RTW, n (%)

F. Baseline characteristics table

	Keele (n=)	Southampton (n=)	London (n=)	Total (n=)
Age, mean (SD)				
Sex, n (%)				
Level of education, n (%)				
Main health condition causing time off work, n (%)				
Aches and pains				
Mental health problems				
Other health condition				
Number of days absence, mean (SD)				
Work interference [WPAI:GH], mean (SD)				
Work performance [SIPQ], mean (SD)				
SF12-PCS, mean (SD)				
SF12-MCS, mean (SD)				
Depression (PHQ-8), mean (SD)				
Anxiety (GAD-7), mean (SD)				
Attitudes & beliefs to work, mean (SD)				
Return to work self-efficacy (RTW-SE), mean (SD)				
Physical activity level (GPPAQ3), n (%)				
Inactive				
Moderately inactive				
Moderately active				
Active				
Use and content of other services providing vocational advice, n (%)				
Vocational advisor				
GP				
My organisation's occ. Health department				
Practice nurse				
Physiotherapist				
Other				
Working hours, n (%)				
Full time (≥35 hours per week)				
Part time (<35 hours per week)				
Work characteristics, n (%)				
Kneeling/squatting for >1 hour per day				
Climbing a ladder				
Climbing up/down stairs >30 times per day				
Digging or shovelling				
Lifting weights of ≥10kg by hand				
Standing/walking for most of the day				
Standing/walking for >3 hours at a time				
Hard physical work that makes you hot/sweaty				

What is the gross total income from all sources per week? n (%)

£0-£99 (£0-£5,199 per year)
£100-£149 (£5,200-£7,799 per year)
£150-£249 (£7,800-£12,999 per year)
£250-£349 (£13,000-£18,199 per year)
£350-£449 (£18,200-£23,399 per year)
£450-£599 (£23,400-£31,199 per year)
£500-£749 (£31,200-£38,999 per year)
£750 or more (£39,00 or more per year)
Prefer not to say

Satisfaction with work, mean (SD)

How do you commute to work? n (%)

Walk
Cycle
Public transport
Car (private or shared)
N/A (e.g. work from home)

How long is your commute to work? Mean (SD)

Health related quality of life (EQ-5D-5L), mean (SD)

WPAI:GH = Work Productivity and Impairment Questionnaire (0%-100%), 0%=no impairment/very high productivity, 100%=greatest impairment/very low productivity; SIPQ = Single Item Performance Question (0-10), 0=health has not affected work performance, 10=health problems are so bad I am unable to do my job; SF12-PCS = Short Form 12v2 Physical Component Scale (0-100), 0=worst physical health score, 100=best physical health score; SF12-MCS = Short Form 12v2 Mental Component Scale (0-100), 0=worst mental health score, 100=best mental health score; PHQ-8 = Patient Health Questionnaire depression scale (0-24), 0=no depression, 24=severe depression; GAD-7 = Generalized Anxiety Disorder (0-21), 0=no anxiety, 21=severe anxiety; Attitudes & beliefs to work (0-60), 0=not impacting return to work, 60=high impact on returning to work; Return to work self-efficacy (RTW-SE, 19 items) (1-10); 1=low self-efficacy, 10=high self-efficacy; EQ-5D-5L (utility) (-0.59 – 1.00), -0.59=Worst health utility, 1.00=Best health utility.

G. 6-week follow-up table

	Keele (n=)	Southampton (n=)	London (n=)	Total (n=)
Main health condition causing time off work, n (%)				
Aches and pains				
Mental health problems				
Other health condition				
Number of days absence, mean (SD)				
Work interference [WPAI:GH], mean (SD)				
Work performance [SIPQ], mean (SD)				
SF12-PCS, mean (SD)				
SF12-MCS, mean (SD)				
Depression [PHQ-8], mean (SD)				
Anxiety [GAD-7], mean (SD)				
Attitudes & beliefs to work, mean (SD)				
Return to work self-efficacy [RTW-SE], mean (SD)				
Physical activity level [GPPAQ3], n (%)				
Inactive				
Moderately inactive				
Moderately active				
Active				
Use and content of other services providing vocational advice, n (%)				
Vocational advisor				
GP				
My organisation's occ. Health department				
Practice nurse				
Physiotherapist				
Other				
Working hours, n (%)				
Full time (≥35 hours per week)				
Part time (<35 hours per week)				
Work characteristics, n (%)				
Kneeling/squatting for >1 hour per day				
Climbing a ladder				
Climbing up/down stairs >30 times per day				
Digging or shovelling				
Lifting weights of ≥10kg by hand				
Standing/walking for most of the day				
Standing/walking for >3 hours at a time				
Hard physical work that makes you hot/sweaty				
Satisfaction with work, mean (SD)				
Perceived change in health condition*, n (%)				

Completely recovered
 Much improved
 Somewhat improved
 The same
 Somewhat worse
 Much worse

WPAI:GH = Work Productivity and Impairment Questionnaire (0%-100%), 0%=no impairment/very high productivity, 100%=greatest impairment/very low productivity; SIPQ = Single Item Performance Question (0-10), 0=health has not affected work performance, 10=health problems are so bad I am unable to do my job; SF12-PCS = Short Form 12v2 Physical Component Scale (0-100), 0=worst physical health score, 100=best physical health score; SF12-MCS = Short Form 12v2 Mental Component Scale (0-100), 0=worst mental health score, 100=best mental health score; PHQ-8 = Patient Health Questionnaire depression scale (0-24), 0=no depression, 24=severe depression; GAD-7 = Generalized Anxiety Disorder (0-21), 0=no anxiety, 21=severe anxiety; Attitudes & beliefs to work (0-60), 0=not impacting return to work, 60=high impact on returning to work; Return to work self-efficacy (RTW-SE, 19 items) (1-10), 1=low self-efficacy, 10=high self-efficacy; EQ-5D-5L (utility) (-0.59 – 1.00), -0.59=Worst health utility, 1.00=Best health utility.

* Perceived change in health condition since completing baseline questionnaire.

H. SMS scores and response rates

	Keele (n=)	Southampton (n=)	London (n=)	Total (n=)
Week 2 SMS				
General health*, mean (SD) [n]				
Have you returned to work?				
Week 4 SMS				
General health*, mean (SD) [n]				
Have you returned to work?				
Week 6 SMS				
General health*, mean (SD) [n]				
Have you returned to work?				
Total responses, n (%**)				
Total number of participants returning to work, n (%)				
Average time to return to work				
Mean (SD)				
Median (IQR)				
Participants responding to 0 texts***, n (%)				
Participants responding to 1 text***, n (%)				
Participants responding to 2 texts***, n (%)				
Participants responding to 3 texts***, n (%)				

Keele - Wolstanton Medical Centre; London - Tessa Jowell GP Surgery; Southampton - Park Surgery

* SMS asking the question: "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?"

** Percent of all SMS messages sent (both for general health and return to work)

*** Where a response to any text at each time point is included