



## Research Article

# Addition of early vocational advice to usual primary care on sickness absence in employed adults: exploratory findings from the discontinued WAVE Randomised Controlled Trial

Gwenllian Wynne-Jones<sup>1\*</sup>, Martyn Lewis<sup>1,2</sup>, Gail Sowden<sup>3</sup>, Ira Madan<sup>4</sup>, Karen Walker-Bone<sup>5</sup>, Carolyn A Chew-Graham<sup>1</sup>, Kieran Bromley<sup>1,2</sup>, Sue Jowett<sup>6</sup>, Vaughan Parsons<sup>3</sup>, Gemma Mansell<sup>7</sup>, Kendra Cooke<sup>2</sup>, Benjamin Saunders<sup>1</sup>, Rosie Harrison<sup>1</sup>, Sarah A Lawton<sup>2</sup>, Simon Wathall<sup>2</sup>, John Pemberton<sup>8</sup>, Julia Hammond<sup>9</sup>, Cyrus Cooper<sup>9</sup> and Nadine E Foster<sup>10</sup>

<sup>1</sup>School of Medicine, Primary Care Centre Versus Arthritis, Keele University, Keele, UK

<sup>2</sup>Keele Clinical Trials Unit, Keele University, Keele, Staffordshire, UK

<sup>3</sup>Connect Health, Newcastle upon Tyne, Tyne and Wear, UK

<sup>4</sup>Occupational Health, Safety and Wellbeing Service, Guy's and St Thomas' NHS Foundation Trust, London, UK

<sup>5</sup>Monash Centre for Occupational and Environmental Health, Monash University, Melbourne, Australia

<sup>6</sup>Health Economics Unit, Department of Applied Health Sciences, University of Birmingham, Birmingham, UK

<sup>7</sup>School of Psychology, College of Health & Life Sciences, Aston University, Birmingham, UK

<sup>8</sup>Research User Group, Impact Accelerator Unit, Keele University, Staffordshire, UK

<sup>9</sup>MRC Lifecourse Epidemiology Centre, University of Southampton, Southampton, UK

<sup>10</sup>STARS Education and Research Alliance, Surgical Treatment and Rehabilitation Service (STARS), The University of Queensland and Metro North Health, Brisbane, Australia

\*Corresponding author [g.wynne-jones@keele.ac.uk](mailto:g.wynne-jones@keele.ac.uk)

Published January 2026

DOI: 10.3310/SVEG8456

## Abstract

**Background and objectives:** To describe exploratory findings and lessons learned from the discontinued WAVE trial, which sought to determine the effectiveness and costs of adding an early vocational advice intervention to usual primary care on number of days of sickness absence over 6 months.

**Methods:** Pragmatic, multicentre, two-parallel arm, superiority, randomised controlled trial with health economic analysis in 10 general practices in England, with nested qualitative interviews. Population: Adults with fit notes for any health condition, absent from work  $\geq 2$  weeks and  $\leq 6$  months were invited to participate. Intervention and comparator: Participants were randomised (1 : 1) to usual primary care with/without vocational advice delivered by trained Vocational Support Workers. The planned sample size was 720, the first 4 months of recruitment served as an internal pilot phase and the primary outcome was self-reported days of work absence over 6 months.

**Results:** One hundred and thirty participants were recruited from 7955 invitations (May 2022–May 2023) before trial closure (64 usual care, 66 usual care plus vocational advice). Exploratory analysis of 125 participants (with outcome data) indicated small additional benefits of the vocational advice intervention over usual care [mean days absence = 37.86 (standard deviation = 48.76) vs. usual care = 42.66 (standard deviation = 57.67), incidence rate ratio = 0.913, 80% confidence interval (0.653 to 1.276)]. The vocational advice intervention was delivered remotely [mean = 4.8 contacts (range 1–12)]. Partial health economic evaluation found lower work productivity losses at 6 months after vocational advice intervention (£5513.84, standard deviation = £7101.43) compared to usual care (£6146.21, standard deviation = £8431.88).

**Conclusions, limitations and future work:** Exploratory analysis indicated a signal of effect, with differences in the number of days absent from work, costs and secondary outcomes. Key lessons learned included the need for

closer working with primary care teams and more flexible recruitment methods. A future fully powered randomised controlled trial of vocational advice intervention added to usual primary care is needed to determine the effectiveness and cost-effectiveness.

**Funding:** This article presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number 17/94/49.

A plain language summary of this research article is available on the NIHR Journals Library Website (<https://doi.org/10.3310/SVEG8456>).

## Introduction

The availability of vocational advice (VA) in the UK is inconsistent and is often limited to employees of larger organisations.<sup>1</sup> Around half of UK employees have access to occupational health services, which vary in quality and effectiveness in supporting return to work (RTW). However, this figure falls to just 26% for those working in small and medium enterprises (businesses with fewer than 250 employees),<sup>2</sup> who employ approximately 61% of the workforce,<sup>3</sup> meaning most people have little to no easy access to occupational health services.

Across Europe, varying policies and systems impact on the delivery of VA, falling into two categories: those that focus on the promotion of access to work for people with disabilities; and those that address VA in a more general sense, ensuring sustainability of social security systems.<sup>4</sup> Some European countries (including the UK, France, Italy and Switzerland) have frameworks for VA but are lacking co-ordination across the different RTW steps (e.g. work-focused health care, RTW planning, referral to occupational health services), meaning VA is only instigated once a person is absent from work often for a predefined period with limited scope for early intervention.<sup>4</sup> The impact of this delayed or lack of access and co-ordinated support can be seen in UK data of new claimants to Employment and Support Allowance (a social security benefit for those looking for work) that show 61% had sickness absence from their last job, 75% of whom decided to stop working themselves.<sup>5</sup> With provision of early VA, in primary care, outcomes may be different.

Due to limited access to occupational health care, it is often the wider non-occupational health services that pick up the responsibility to support people to work. This is undertaken in the UK through the Statement of Fitness for Work (commonly known as the 'fit note'), introduced in 2010.<sup>6</sup> A fit note recommends whether a patient is fit for work or may be fit for some work with adjustments. Despite the fit note's structure to aid completion, many clinicians lack confidence in providing VA and are unsure how to have good work-orientated conversations with patients, potentially leading to longer-term absences

and poorer health outcomes.<sup>7</sup> The fit note can be issued by doctors, nurses, pharmacists, physiotherapists and occupational therapists and can be used in both primary and secondary care, although most are provided in primary care.<sup>6,8</sup> A person does not have to be seen or spoken to for a fit note to be issued and many are issued online.<sup>9</sup>

While research into the delivery of early VA has been undertaken, much of it focuses on specific health conditions<sup>10,11</sup> or workplace interventions<sup>12,13</sup> rather than the interface between health and work. Integrated health and VA models in countries such as Sweden and the Netherlands have shown effectiveness in reducing work absence and healthcare use.<sup>14,15</sup> In the UK, our previous Study of Work And Pain (SWAP) randomised controlled trial (RCT) demonstrated the benefits of early VA for adults with musculoskeletal (MSK) pain, reporting a difference of 5.1 days in favour of a VA intervention {9.3 [standard deviation (SD) 21.7] days in the intervention arm (VA intervention plus usual primary care) compared with 14.4 (SD 27.7) days in the control arm (usual primary care alone)}, with an adjusted incidence rate ratio (IRR) of 0.51 ( $p = 0.048$ ). An exploratory subgroup analysis of SWAP data suggested that those with at least 2 weeks of work absence were more likely to benefit from the addition of the VA intervention.<sup>10</sup> The SWAP trial also highlighted the economic case for early VA, estimating significant cost-savings and health benefits.<sup>10</sup> Offering VA early in primary care could address the current lack of universal provision, reduce absence and improve patients' quality of life, as well as lead to societal benefits from active workforce engagement.

The Work And Vocational advice (WAVE) trial aimed to investigate the effectiveness and costs of adding a brief VA intervention to usual primary care in reducing the number of days absent from work over a period of 6 months in adults who receive a fit note from their general practice.

The trial is reported with reference to the CONSERVE-CONSORT Extension for reporting trials modified due to the COVID-19 pandemic.<sup>16</sup>

### **Extenuating circumstances: effects of COVID-19 on the WAVE trial**

The WAVE trial was designed in 2017–8, submitted for funding in May 2018, funded in December 2018 and commenced its funded timeline in June 2019, comprising a feasibility phase with stop/go criteria, an internal pilot RCT phase with stop/go criteria and a main RCT phase. The feasibility phase was planned to commence Vocational Support Worker (VSW) training in April 2020, recruit patients from May to July 2020, with intervention delivery and follow-up through to November 2020. Participant recruitment in the internal pilot RCT phase was due to take place from December 2020 to March 2021 and, in the main RCT, from April 2021 to December 2022. The consequences of the COVID-19 pandemic from March 2020 in the UK severely affected the trial, both delaying the start of VSW training and patient recruitment as well as severely hampering recruitment. The new timeline for the feasibility phase meant that commencement of patient recruitment at general practices in December 2021 coincided with general practices mobilising the COVID-19 vaccine roll-out in the UK.<sup>17</sup> Not only was general practice under immense pressure delivering vaccines, but it was also undergoing a rapid shift from predominantly in-person to telehealth consultations.<sup>18</sup> Adults struggling with work could self-certify a period of absence for up to 7 days before the pandemic, but this period was extended to 28 days at the height of the pandemic to protect primary care appointments.<sup>19</sup> As the WAVE trial patient identification was based on fit notes coded in the general practices' medical record system, the change, although temporary, impacted recruitment. Measures to reduce patient 'footfall' in general practices included a switch to online fit notes, whereby patients completed an online form which was then sent to their clinician as a 'task' to electronically sign.<sup>9</sup> Trial recruitment anticipated the use of an automated electronic medical record (EMR) protocol during 'real-time' consultations with clinicians asking patients for consent for the research team to contact them with an invitation to the trial (method 1 of 3). The online fit note meant that recruitment methods could not work as anticipated and modifications were needed.

Alongside changes in general practice, the UK workforce was undergoing the shift to home working where possible. Where not possible, many employers utilised the Government 'furlough scheme' aimed at providing 80% of an employees' salary for the hours they were unable to work.<sup>20</sup> This change meant many did not need to access their general practice for a fit note authorising work absence, as they were either furloughed or able to manage to work from home with their health condition.<sup>21</sup>

Given the above, modifications were made to the WAVE trial protocol to support recruitment and the approach to analysis, given the lower than anticipated response rate to invitations to the trial. Decisions about these modifications were made by the Trial Management Group (TMG) with advice from the Trial Steering Committee (TSC) and funder where necessary.

### **Modifications**

The main modification made to the trial was that recruitment approaches became more automated, and a third recruitment method was introduced identifying potential participants using back-dated searches of the general practice EMR (method 3 of 3), and instead of a full study pack, potentially eligible participants were posted an invitation letter containing a link to an online eligibility screen and consent to contact form. This method was included after the publication of the protocol paper.<sup>22</sup> Despite changes to recruitment, the objectives remained the same and intervention delivery was unchanged, having been planned to be remote prior to the pandemic.

Despite changes to recruitment, close monitoring of the identification and recruitment numbers using each recruitment method and close communication with participating practices, the WAVE trial recruited a mean of only 13.1 patients per 'active' trial month in comparison to the 41.7 patients per month needed to reach our target sample size. With the agreement of the funder, TSC and TMG, recruitment to the trial closed in April 2023. The last participant was randomised in May 2023 (allowing for those in process to enter the trial if they gave informed consent and completed the baseline questionnaire).

The analysis plan reported in the protocol paper was also modified, given the low recruitment rates, as follows:

- A zero-inflated negative binomial model was to be fitted to assess the effect of the addition of the VA intervention compared to usual care alone in reducing the number of days off work over 6 months, adjusting for region, health condition resulting in time off work {[MSK, mental health (MH) or 'other' condition]} and time off work due to the health condition at entry to the trial. The inclusion of several other covariates was planned, but these had to be removed due to the reduction in power resulting from the reduced sample size.
- The overall aim of the analyses was modified to explore whether there was a 'signal of effect' rather than effectiveness of the addition of the VA intervention to usual care alone, by focusing on the

width of confidence intervals (CIs) (including 80% as well as 95% CIs) and not on *p*-values.

- Health economic analyses were planned to be a cost-effectiveness analysis; however, this was modified to determine the costs of offering the VA intervention and comparing productivity losses due to time off work between trial arms. The objective of our health economic analysis was updated to reflect this change.
- The planned full economic evaluation was not undertaken due to the reduced sample size and due to healthcare resource use questions being omitted from the 6-month questionnaire in error.

## Objectives

### 1. Primary objective:

To investigate the effectiveness of adding a brief VA intervention to usual primary care in reducing the number of days absent from work over a period of 6 months in adults who receive a fit note from their general practice.

### 2. Secondary objectives:

- Determine the NHS costs of offering the VA intervention and compare productivity losses due to time off work between trial arms.
- Investigate time to RTW and compare this between trial arms.
- To explore factors mediating observed differences in outcomes between the trial arms (increased RTW self-efficacy, positive change in health symptoms, reduced fear avoidance beliefs, increased participation in everyday life, workplace contact and adjustments in work activities).

Alongside the trial, nested qualitative interviews were undertaken to explore and understand the perspectives and experiences of trial participants, VSWs, primary care clinicians and employers/line managers about decision-making around work absence and RTW. These also explored participants' experiences of receiving, and the acceptability of, the VA intervention and its delivery in practice and are reported separately (Harrison *et al.*, 2025: <https://bjgpopen.org/content/early/2025/11/02/BJGPO.2024.0280.long>).

## Methods

### Trial design

The methods are reported in full in the published protocol.<sup>22</sup> The WAVE trial was a multicentre, pragmatic, two-parallel arm, superiority RCT with a health economic evaluation and nested qualitative interviews.

### Setting

Ten general practices in the National Institute for Health and Care Research Regional Research Delivery Network (RRDN) areas of the West Midlands, Wessex and South London regions in England; each RRDN supports the delivery of research within health and social care.

### Eligibility criteria

Eligibility criteria included: adults over 18 years; in paid employment (full-time or part-time); current absence from work of at least 2 consecutive weeks but not more than 6 continuous months and had received a fit note. Exclusion criteria included: long-term absence defined as over 6 continuous months; pregnant or on maternity leave; signs or symptoms indicative of serious pathology ('red' flags); severe MH problems or high vulnerability,<sup>22</sup> for example people in the palliative stages of illness, those experiencing a recent bereavement and those with dementia.

### Identification and recruitment

Potentially eligible patients were identified when they were issued with a fit note in general practice (the full methods are published in the protocol<sup>22</sup>).

Three methods of identification and invitation were used to recruit participants:

1. Identification through an automated EMR protocol during 'real-time' consultations.
2. Identification through searches of the general practice EMR after consultation where a 'pop-up' is fired on completion of a fit note.
3. Identification through back-dated searches of the general practice EMR identifying patients issued a fit note with (1) study pack posted or (2) link to a consent to contact form.

A study pack (or link to consent to contact) was sent to potentially eligible patients, including participant information, consent form, questionnaire with screening questions to confirm eligibility (reported in the protocol) and a prepaid reply envelope.<sup>22</sup>

### Trial oversight

The trial was overseen by independent TSC and Data Monitoring Committee (DMC), in addition to monthly TMG meetings throughout.

### Randomisation and allocation concealment

Participants were individually randomised by computer-generated, stratified block randomisation (ratio 1:1). Stratification took place based on region (West Midlands, Wessex and South London) and main health condition for which the fit note was issued (MSK condition, mental

ill health or 'other'). Participants, their treating clinicians and the VSWs who delivered the intervention could not be blinded to allocation. Members of the trial team were blinded, and analysis was undertaken independently by one statistician (unblinded, to allow reporting to trial committees as required) with oversight by a second who was blinded to allocation.

### Interventions

The usual care alone arm was able to access usual care delivered by their primary care team, which does not include formal VA.

The usual care plus VA arm had access to usual care from their primary care team alongside VA delivered early in their sickness absence as part of the trial. The development, delivery and training of VSWs in the VA intervention is reported in full elsewhere (Sowden *et al.*, under review, and in the protocol<sup>[22]</sup>). Briefly, the intervention was developed through a best evidence review of published literature, reports and educational materials to draft a logic model. This logic model was then subject to review and amendment by experts, employees and academics with experience in work and health. The intervention was delivered remotely (via phone or video conferencing) using the principles of stepped care and case management, with VSWs working with participants to identify obstacles to

working, creating a RTW plan and assessing this at subsequent consultations (Figure 1). The intervention was considered to be delivered if VSWs had at least one phone call where they provided evidence-based information, discussed obstacles to work and developed a RTW plan. VSWs received 4 days of training, with a half-day refresher prior to recruitment commencing, and they were supported by monthly supervision sessions to facilitate peer support and learning. Participants continued to be eligible for VSW support until they reached a sustained RTW, defined as remaining in any work for 4 consecutive weeks,<sup>23</sup> or until they had been absent from work for a total of 6 months.

Adverse events were defined as any untoward medical occurrence. If VSWs felt that a medical occurrence was related to the trial intervention, then they followed a protocol for reporting any issue, that met the definition of an adverse event, to the Trial Manager and Chief Investigator.

### Outcomes

The primary outcome was the number of days off work over 6 months based on the following self-report question: 'How much time off work during the past "x" months have you had because of your health condition? Where "x" refers to the period between questionnaires. Please write the total number of days you were off work due to your

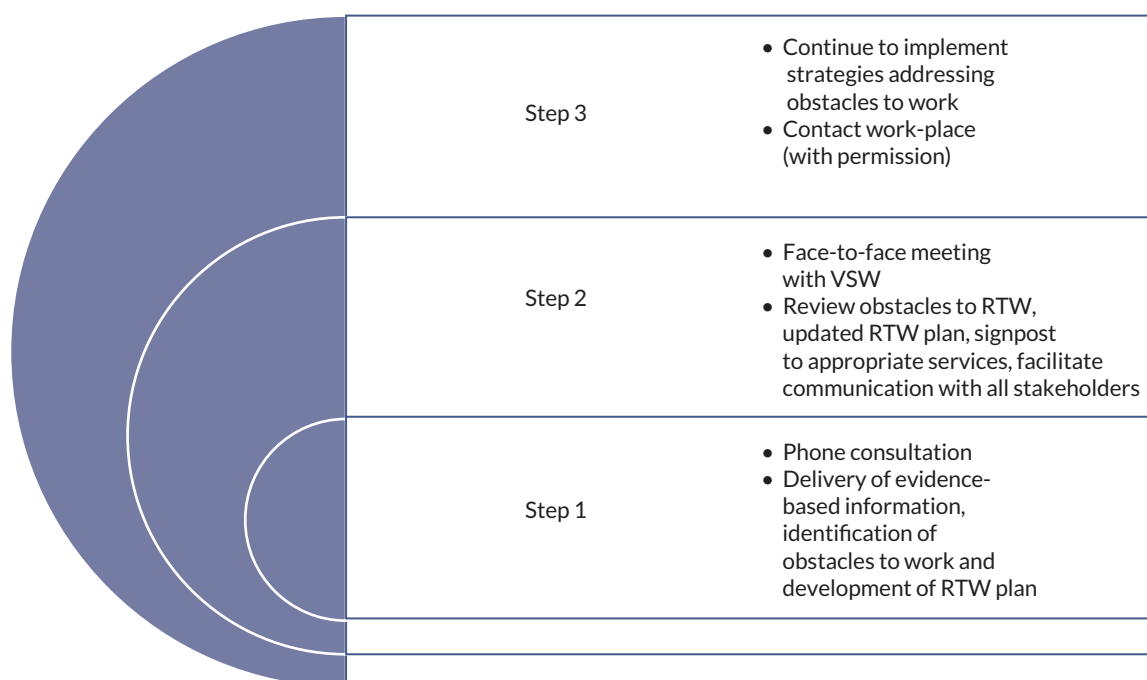


FIGURE 1 Diagram of the VA intervention structure and content.

health condition'. Time off work data were summed across the 6-week and 6-month questionnaires.

Participants also received fortnightly SMS text messages to determine whether they had returned to work. Data collected from text messages asked participants if they had returned to work – 'Yes/No'; if participants responded 'Yes', then a second message was sent asking them to report the date of return day/month/year, and later, whether they had remained off work. Based on these dates, the number of days of absence was calculated. SMS messages were sent either until participants had reached sustained RTW or reached the end of study follow-up. Full details of all outcome measures are included in the protocol.<sup>22</sup>

### Statistical analyses

#### Internal pilot

An internal pilot RCT phase ran over the first 4 months of recruitment, with progression criteria: Stop (Red)/Amend (Amber)/Go (Green), including:

1. recruitment uptake  $\leq$  70% of those eligible and consenting to participate (Red), 71–99% (Amber), 100% (Green)
2. engagement with the VA intervention, percentage of VA intervention arm participants who have at least one contact with a VSW  $<$  40% (Red), 40–65% (Amber),  $>$  65% (Green)
3. rate of follow-up on the primary outcome data at 6 weeks  $<$  60% (Red), 60–80% (Amber),  $>$  80% (Green).

A decision to continue to the main trial was made based on progression criteria being met at the 'Green' level and to continue, but with some adjustments, if any criteria were at least 'Amber'; the trial could be stopped if any of the criteria were 'Red' and the TMG, TSC and DMC agreed that they could not be addressed.

#### Main trial

Missing time off work data were imputed from SMS text messages to count the number of days off work, where for each week off work, either 2 of 5 days were imputed for part-time or full-time workers, respectively, to maximise data for analysis. There was no pattern to missingness which appeared to be at random. A zero-inflated negative binomial model was fitted to assess the effect of the addition of the VA intervention versus usual care alone in reducing the number of days off work over 6 months, adjusting for region, primary health condition resulting in time off work (MSK, MH or 'other' condition) and time off work due to the health condition(s) 6 months prior to randomisation. Analysis focused on reporting parameter

estimates and associated 80% CIs (in addition to 95% CIs), with *p*-values not disclosed.

### Sensitivity analyses

1. Investigation of the individual components of the VA intervention reporting time off work for each level delivered (steps 1–3).
2. To test the assumptions made in the primary analysis, differences between arms were calculated at 6 weeks and 6 months separately, both with and without imputed SMS data, as well as with/without part-time or full-time work.

### Mediation analysis

A mediation analysis was planned to test for hypothesised causal pathways between variables thought to be important in explaining any between-arm differences in the primary outcome (days absent from work over 6 months). Data on potential mediators were collected at baseline, 6 weeks and 6 months. Simple regression models were constructed to test the associations between intervention arm allocation and scores on each potential mediator at 6-week follow-up (*a* pathway) and to test the associations between scores on each potential mediator at 6-week follow-up and days absent from work at 6-month follow-up (*b* pathway). These analyses allowed exploratory examination of whether allocation to the VA intervention arm may be associated with a change in any of the potential mediators and also whether change in the potential mediators was associated with improvement days absent from work. Mediation analysis was only performed where associations were present.

### Health economic analysis

A partial health economic evaluation was undertaken from an NHS perspective, with secondary analysis from a societal perspective considering indirect (productivity) costs. The planned full economic evaluation was not undertaken due to the reduced sample size and also due to the healthcare resource use questions being omitted from the 6-month questionnaire in error.

For the VA intervention arm, participant-level costs were calculated, considering the time taken for all contacts with the VSW, using unit costs specific to the salary band of the VSW. Costs of training the VSWs were also calculated. Health-related quality of life (HRQoL) was measured using the EuroQoL-5 Dimensions, five-level version (EQ-5D-5L) questionnaire. Productivity costs were calculated by multiplying the days of work absence by occupation-specific average gross wage using SOC2020 codes.<sup>24,25</sup>

### Sample size

The trial was designed to detect a 25% reduction in days off work over 6 months between the two arms, equating to an IRR of 0.75 (e.g. mean days off work reduced from 30 days after usual care alone to 22.5 days when the VA intervention is added to usual care). A sample size of 720 would have given 80–90% power to detect the IRR of 0.75 based on a 5% two-tailed significance and an assumed dispersion parameter of 1.4 (derived from a previous trial<sup>10</sup>), allowing for 20% loss to follow-up. The trial was closed to recruitment after 130 participants were recruited, given pervasive recruitment challenges.

Given the reduced sample size, a post hoc power calculation was carried out. To detect the preset IRR of 0.75, based on an analysis sample size of 125 who had outcome data (64 and 61 per arm), the power was 0.26 and 0.51 for a two-tailed alpha of 0.05 (to provide evidence of effect) and 0.2 (to provide signal of effect), respectively. The power is increased to 0.64 and 0.85, respectively, if the true IRR is 0.6. The dispersion of the data analysed, under the zero-inflated negative binomial model, was slightly higher than previously anticipated at 1.51.

### Patient and public involvement and engagement

Patient and public involvement and engagement (PPIE) was included in the WAVE trial from the development of the research question through to dissemination. Meetings were held with PPIE members (prior to grant submission) to help develop a relevant research question, and then throughout the trial, to support development of participant-facing materials and to advise on study progress and modifications in particular recruitment. Throughout the trial, a PPIE member joined the trial management team and supported all publications, and two members participated in the TSC.

## Results

### Internal pilot RCT phase

Due to the challenges in recruitment, a formal pilot RCT phase analysis was not undertaken. However, an assessment was made against the progression criteria for the purposes of reporting to the TSC and DMC committees. Ninety-three participants were recruited up to November 2022; all those who were eligible and consented were recruited into the trial, meeting the progression criteria (1) (recruitment uptake). Of those who were recruited to the VA intervention arm, all participants had at least one contact with the VSW, meeting progression criteria (2), and of those who had reached the 6-week follow-up, 44 of 45 participants (98%) completed the primary outcome

measure, meeting progression criteria (3). The decision was therefore made to continue to the full trial.

### Recruitment

A total of 130 participants consented and were recruited between May 2022 and May 2023, from 7955 invitations sent. *Figure 2* reports the flow of participants through the trial. The VA intervention arm included 66 participants and usual care intervention arm included 64, with 76% and 68% follow-up rates at 6 weeks and 6 months, respectively, in the VA intervention arm, and 75% and 77% in the usual care alone arm.

### Baseline characteristics

*Appendix 1, Table 5* shows that participants were broadly comparable between arms at baseline. Average number of days of work absence in the 6 months before trial recruitment was 34.65 days in the VA intervention arm and was 33.73 days in usual care alone. Those in usual care alone reported slightly more mental ill health conditions (39.1%), more full-time working (79.0%) and more inactivity (39.7%) compared to the VA intervention arm.

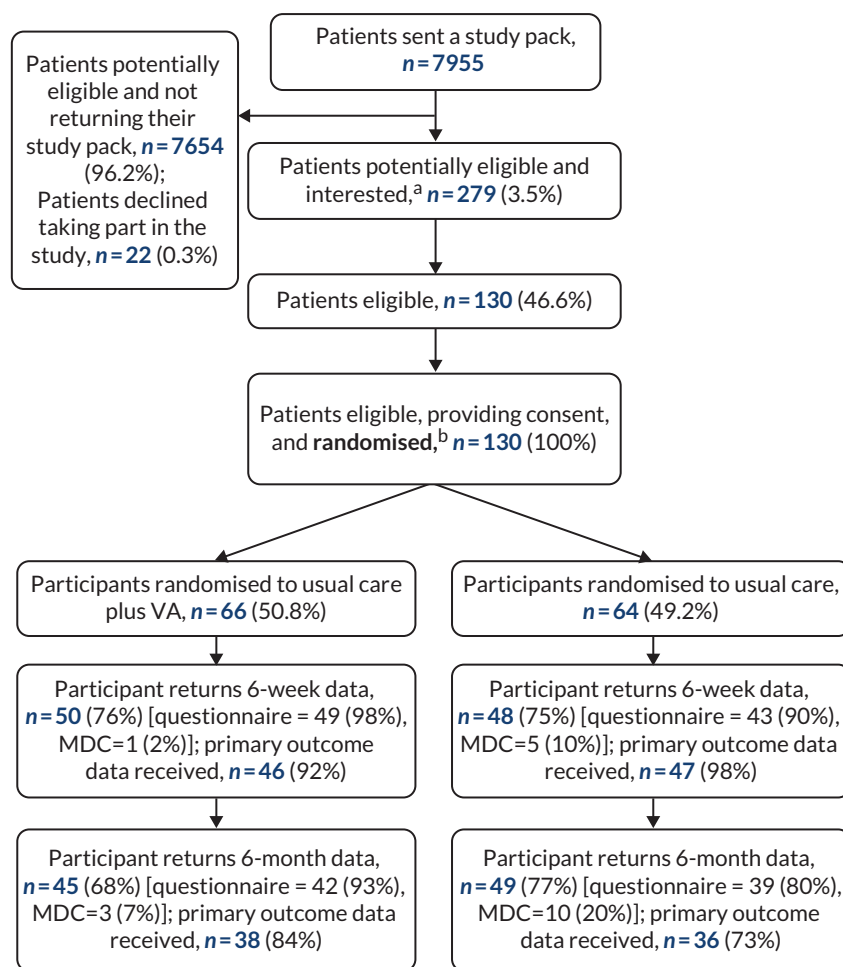
### Delivery of the vocational advice intervention

Contact from a VSW was attempted with 52 participants in the VA intervention arm (52/66 = 78.8%). All participants were contacted by phone at least twice, with the total number of phone contacts (including setting up appointments and delivering the intervention) being 305 (mean = 5.87, SD = 3.25), ranging from 2 to 14 contacts. Of these, 45 VA intervention participants (45/52 = 86.5%) answered phone calls from the VSW for a total of 216 times (mean = 4.80, SD = 2.42), ranging from 1 to 12 times. The VA intervention was delivered to 44 participants (44/66 = 66.6% of those randomised, 1 participant declined the intervention when contacted) in 162 phone calls (mean = 3.68, SD = 2.48), ranging from 1 to 11 times. One video call was conducted to deliver the VA intervention. Thirteen participants were e-mailed as part of their VA intervention [average 4.77 e-mails (SD = 9.53)], range (1–36). E-mails were used to arrange appointments, provide VA information to participants and for participants to update the VSW on their progress. No in-person meetings were required. In total, 279 contacts were made by the VSWs (216 phone calls, 1 video call, 62 e-mails).

No adverse events were reported.

### Primary outcome

At 6 months, there was some evidence of a between-arm difference in the number of days absent from work after imputing missing data from SMS text messages, with



**FIGURE 2** Participant recruitment. Withdrawals: usual care plus VA:  $n = 5$  (45.5%); usual care: 6 (54.5%). a The patient has returned their study pack containing their consent form and questionnaire (consent and baseline questionnaire are combined). Potentially eligible, potentially eligible to take part in the trial according to the site criteria (i.e. fulfilling all inclusion/exclusion criteria at trial site assessment). Interested, full/partial completion of either or both the baseline questionnaire and/or consent form. b The patient has not yet returned to work and provided full consent to participate in the trial. MDC, minimum data collection.

those in the VA intervention arm reporting fewer days off work at a mean of 37.86 (SD 48.76) days compared to the control arm mean of 42.66 (SD 57.67) days with an adjusted IRR of 0.913 (80% CI 0.653 to 1.276). While there was no apparent difference in absence over 6 months by either region or health condition, more time off work prior to randomisation was associated with longer time to RTW [IRR 1.009, 80% CI (1.002 to 1.015)] (Tables 1 and 2).

Data from the SMS text messaging reporting sustained RTW showed that by 6-month follow-up, 69.7% in the VA intervention arm and 71.9% in the control arm had achieved a sustained RTW, with a further 7.6% and 3.1%, respectively, having returned to work but not yet achieved 4 consecutive weeks at work.

### Exploratory subgroup analyses

Subgroup analyses indicated no apparent between-arm differences for health conditions when comparing

'other' conditions with MH or MSK. However, there were differences when comparing by absence duration, indicating that those in the VA intervention arm reported more short-term absence at a mean of 27.84 (SD = 43.80) days compared to the usual care alone arm (see Appendix 3, Table 7).

### Sensitivity analyses

To explore potential effects of VA intervention 'dose', that is the amount of intervention each participant received as measured using the step of intervention participants reached, the mean number of days off based on step of the VA intervention received was assessed (see Appendix 4, Table 8). There was no clear pattern in absence over 6 months by the step of intervention received, although those receiving step 1 (telephone call to discuss the participants health and work situation) reported fewer mean days absence than other subgroups at 28.66 days (SD 43.93).

**TABLE 1** Comparison of absence data at 6 weeks and 6 months in participants receiving VA intervention plus usual care as compared with those receiving usual care alone

Outcome	$N_{\text{Int}}$ $N_{\text{Cont}}$	VA intervention plus usual care (n = 66)	Usual care alone (n = 64)	Total (n = 130)	Unadjusted IRR (80% CI)	Adjusted IRR (80% CI)
<b>Primary analysis model</b>						
Number of days absence over 6 months from questionnaires and SMS (using PT and FT), <sup>a</sup> mean (SD) (median, IQR)	64, 61	37.86 (48.76) (14.93, 0–45.64)	42.66 (57.67) (10, 4–77)	40.20 (53.13) (12, 1–52)	0.976 (0.705 to 1.352)	0.913 (0.653 to 1.276)
<b>Questionnaire data</b>						
Number of days absence over 6 months (complete case), mean (SD) (median, IQR)	30, 33	45.57 (56.57) (10.5, 0–30)	54.76 (66.01) (7, 0–30)	50.33 (61.38) (9, 0–30)	1.007 (0.638 to 1.590)	0.931 (0.562 to 1.541)
Number of days absence over first 6 weeks, mean (SD) (median, IQR)	46, 47	16.72 (16.98) (0, 0–45.5)	15.81 (17.09) (3.5, 0–46)	16.26 (16.95) (0, 0–45.5)	1.138 (0.870 to 1.488)	0.999 (0.747 to 1.335)
Number of days absence between 6 weeks and 6 months, mean (SD) (median, IQR)	38, 36	30.29 (50.13) (20, 0–76.75)	33.14 (50.57) (15, 5–100)	31.68 (50.02) (16, 1–86.5)	1.315 (0.780 to 2.221)	1.326 (0.770 to 2.285)
<b>Sensitivity analyses</b>						
Number of days absence over first 6 weeks (questionnaire + SMS), mean (SD) (median, IQR)	64, 62	14.50 (14.71) (10, 0–30)	15.09 (15.25) (9.5, 0.25–30)	14.79 (14.92) (9.64, 0–30)	1.035 (0.840 to 1.274)	0.997 (0.809 to 1.228)
Number of days absence between 6 weeks and 6 months (questionnaire + SMS), mean (SD) (median, IQR)	65, 61	23.02 (39.81) (0, 0–32)	27.37 (45.05) (0, 0–35)	25.13 (42.31) (0, 0–32.43)	0.989 (0.670 to 1.459)	0.949 (0.635 to 1.416)
Number of days absence over 6 months from questionnaires and SMS, <sup>b</sup> mean (SD) (median, IQR)	64, 61	51.86 (61.19) (23, 0–87.75)	52.80 (64.04) (20, 3–84)	52.32 (62.34) (22, 1–85)	1.099 (0.820 to 1.473)	1.052 (0.775 to 1.428)

FT, full-time; IQR, interquartile range;  $N_{\text{Cont}}$ , number in usual care alone;  $N_{\text{Int}}$ , number in VA intervention plus usual care; PT, part-time.  
 a Where available, where the participant had reported being PT or FT, any missing period imputed by SMS was assumed to be 2 days if PT, and 5 days if FT. SMS data were used to provide a full timeline of time off work over the 6-month follow-up period only where there were gaps in the questionnaire data. When PT/FT was not assumed, the total number of days over the period was used.  
 b Assuming all days off over the period was time off work.

**TABLE 2** Number of days absence over 6 months from questionnaires and SMS (using PT and FT data)

Variable	Unadjusted IRR (80% CI)	Adjusted IRR (80% CI)	Unadjusted IRR (90% CI)	Adjusted IRR (90% CI)	Unadjusted IRR (95% CI)	Adjusted IRR (95% CI)
Arm	0.976 (0.705 to 1.352)	0.913 (0.653 to 1.276)	0.976 (0.643 to 1.482)	0.913 (0.594 to 1.403)	0.976 (0.593 to 1.606)	0.913 (0.547 to 1.523)
<b>Region</b>						
Wessex	–	1.146 (0.749 to 1.752)	–	1.146 (0.664 to 1.976)	–	1.146 (0.598 to 2.193)
West Midlands	–	0.966 (0.625 to 1.494)	–	0.966 (0.553 to 1.690)	–	0.966 (0.497 to 1.881)
Baseline time off work (days)	–	<b>1.009 (1.002 to 1.015)</b>	–	<b>1.009 (1.001 to 1.016)</b>	–	1.009 (1.000 to 1.018)
<b>Health condition</b>						
MH	–	0.947 (0.616 to 1.454)	–	0.947 (0.546 to 1.642)	–	0.947 (0.491 to 1.824)
MSK	–	1.000 (0.666 to 1.503)	–	1.000 (0.593 to 1.687)	–	1.000 (0.537 to 1.864)

**Note**

Reference groups: Arm = usual care; Region = South London; health condition = none or other. Baseline time off work, recorded as time off work before randomisation over the previous 6 months. A greater IRR indicates a greater number of days remaining off work in the usual care arm versus the usual care plus intervention arm.

### Secondary analysis

Exploratory analyses of secondary outcomes at 6 weeks (see [Appendix 5, Table 9](#)) indicated that those in the VA intervention arm reported lower mean absenteeism, presenteeism, work productivity loss and activity impairment on the Work Productivity and Activity Impairment (WPAI) scale<sup>26</sup> than the usual care alone arm. Participants in the usual care alone arm were less likely to have contact with their employing organisation's occupational health department (where available) than those in the VA intervention arm [odds ratio (OR) 0.424 (80% CI 0.202 to 0.857)]. Those in the usual care alone arm were significantly more likely to report lower quality of life measured with the EQ-5D-5L at a mean of 0.56 (SD 0.30) compared to a mean 0.71 (SD 0.22) in the VA intervention arm [mean difference -0.080 (80% CI -0.136 to -0.024)]. At 6 months, the same pattern was seen in the data, although the difference in EQ-5D-5L was less marked (see [Appendix 6, Table 10](#)). SMS data suggested that the rate of sustained RTW in the usual care alone arm was slightly greater than for those in the VA intervention arm [hazard ratio 0.939 (80% CI 0.723 to 1.221)].

### Mediation analysis

Full mediation analysis was not possible due to the small sample size. However, tests of the *a* path for each mediator only found statistically significant mean differences for arm allocation on quality of life at 6-week follow-up (EQ-5D-5L<sup>27</sup>). Adjusted *R*<sup>2</sup> values suggested that arm allocation explained < 1% of variance in any of the potential mediators (see [Appendix 7, Table 11](#)).

Tests of the *b* path in each intervention arm separately (see [Appendix 7, Table 11](#) and [Appendix 8, Table 12](#)) found that improved physical health [Short Form questionnaire-12 items (SF-12) physical component score (PCS)<sup>28</sup>], improved depression scores (Patient Health Questionnaire-9 items<sup>29</sup>), improved RTW self-efficacy scores and improved

quality-of-life (EQ-5D-5L<sup>27</sup>) score at 6-week follow-up were significantly associated with a reduction in days absent from work at 6-month follow-up in both treatment allocation arms. Increased impact of health problems on work (work performance), increased absenteeism, increased presenteeism, worsened productivity and increased impairment at 6-week follow-up were significantly associated with increased number of days absent from work at 6-month follow-up in both arms. The proportion of the variance explained was highest for work absenteeism, productivity, physical health, work performance and quality of life (see [Appendix 7, Table 11](#)).

Additional significant associations were seen for depression, MH [SF-12 mental component score (MCS)<sup>28</sup>] and anxiety at 6-week follow-up in the usual care alone arm compared to the VA intervention arm. However, only small numbers of participants are included in these analyses, and the distribution of some of the work variables means caution must be taken in interpreting the results.

### Health economic analysis

The health economic analysis focused on a comparison of direct (productivity costs) between arms. The VA intervention arm was associated with lower productivity losses of £5513.84 (SD £7101.43) compared to the usual care alone arm with a productivity loss of £6146.21 (SD £8431.88); this difference remained when using participant specific wages (as reported in the baseline questionnaire) ([Table 3](#)).

The cost of the VA intervention was calculated using staff costs from the Unit of Costs of Health and Social Care 2023.<sup>30</sup> VSWs were graded at NHS Agenda for Change salary band 5 or 6, and costs were inclusive of salary, oncosts and overheads. Considering the salary band of the VSW, the mean cost of the VA intervention per participant was £70.14. Assuming all VSWs were band 6, this cost

TABLE 3 Productivity loss estimates

Outcome	<i>N</i> <sub>Int</sub> , <i>N</i> <sub>Cont</sub>	VA plus usual care			Difference (VA intervention: usual care alone) <sup>a</sup> (95% CI) (80% CI)
		( <i>n</i> = 66)	Usual care ( <i>n</i> = 64)	Total ( <i>n</i> = 130)	
Productivity loss (using average wage for all) (using PT and FT), mean (SD) £	64, 61	5513.84 (7101.43)	6146.21 (8431.88)	5822.44 (7753.98)	632.37 (-2049.21 to -3382.36) (-1136.37 to -2405.19)
Productivity loss using participant specific wage (using PT and FT), mean (SD) £	64, 61	4665.78 (6438.02)	5699.33 (7569.16)	5170.15 (7003.52)	1033.55 (-1484.29 to -3542.14) (-601.83 to -2645.21)

a Unadjusted difference with bias corrected bootstrapped CI (5000 replications). Costed using Annual Survey of Hours and Earnings gross wages from 2021.

increased to £82.32 and decreased to £63.68 if all were band 5. Due to the large variability in VSW interactions with participants, the cost per participant ranged from £6.83 to £302.72 (Table 4).

In addition to the costs of delivering the VA intervention, the costs of training and supervision were calculated (assuming a band 7 staff member delivers training, band 8a provided in brackets): main training total cost £1152 (£1728), cost per VSW ( $n = 3$ ) £504 (£576) and half-day refresher training £252 (£288). Monthly supervision during the VA intervention delivery period was estimated to cost £504 (£576) per VSW.

## Discussion

The WAVE trial aimed to evaluate the effectiveness and costs of adding a brief early VA intervention to usual primary care in reducing work absence over 6 months for adults receiving a fit note from their general practice. Due to recruitment challenges, the trial was stopped early and was underpowered to detect the significant differences between the two arms. Analysis was undertaken to assess whether there was a 'signal of effect' that may justify further exploration of VA interventions in primary care. We believe that the analyses, while underpowered, suggest that adding a brief and early VA intervention shows a promising signal of effect, with 4.8 fewer days absent from work on average over 6 months, and a range of outcomes also favouring the VA intervention arm at 6 weeks (lower presenteeism and activity impairment yet improved quality of life). However, the mean differences noted had large SDs and absence did not meet the 25% reduction that we aimed to achieve. Importantly, the VA intervention had a mean cost of £70.14 per participant, excluding costs associated with training VSWs, and was associated with reduced productivity losses (£5513.84 vs. £6146.21). Larger RCTs with adequate power are likely justified in future and could benefit from the learning from the WAVE trial.

This trial provides important lessons for developing evidence on VA services delivered in healthcare settings. The key lessons are that closer working with primary care teams is required to strengthen 'buy-in' if RCTs about work are to be undertaken within this setting, methods of recruitment need to be agile to address the changing primary care landscape which varies locally and is influenced by the wider sociopolitical context. The focus on work and the sensitivity of this topic for participants means that assumptions around recruitment rates need to be carefully considered and recruitment periods may need to be lengthened. It would also be of value to explore the potential to deliver VA interventions in other settings, for example other community healthcare services or workplaces.

### Comparison with wider literature

Current UK policy initiatives are exploring the delivery of VA through the UK's WORKWELL initiative testing the integration of VA with health care and work training programmes, alongside the creation of new roles for employment advisors within MSK services.<sup>31-33</sup> The impact of COVID-19 on studies of health and work has been explored, identifying that opportunities to screen and consent participants into studies were reduced.<sup>34</sup> This finding is in line with the challenges seen in the WAVE trial, where the planned recruitment methods were affected by COVID-related changes in primary care. There are few comparative trials of VA delivered within healthcare settings during the COVID-19 pandemic, but those that have reported outcomes also struggled to recruit. A Norwegian trial set in an integrated health and social security system and recruiting workers with MSK conditions recruited 25% of those potentially eligible. That trial was temporarily halted because of COVID-19 containment measures, although it did almost reach their target sample size albeit over an extended time period.<sup>11</sup> A UK trial providing early specialist stroke vocational rehabilitation also reported challenges in recruitment because of the COVID-19 pandemic.<sup>35</sup> That trial recruited over an extended period and closed before reaching the

**TABLE 4** Cost of the VA intervention per participant ( $n = 52$ )

	VSW-specific costs (£) (actual costs within the WAVE trial)	Salary band 5 costs (£) (estimated cost)	Salary band 6 costs (£) (estimated cost)
Mean (SD)	70.14 (59.53)	63.68 (55.36)	82.32 (71.56)
95% CI	54.30 to 85.97	48.64 to 78.72	62.94 to 101.70
80% CI	59.85 to 80.42	53.68 to 73.68	69.31 to 95.33
Range	6.83 to 302.72	6.83 to 302.72	8.83 to 391.32

planned sample size, with the authors noting that changes in the 'meaning' of work in peoples' lives as a result of the pandemic influenced their trial's ability to recruit.<sup>35</sup> Lastly, a pilot trial of an Individual Placement and Support intervention for those unemployed for > 3 months with chronic pain, conducted before the COVID-19 pandemic, also struggled to recruit participants through primary care despite a range of recruitment methods.<sup>36</sup> Those authors noted the lack of a whole-system approach to health and employment so that not only was employment status absent or poorly recorded in primary care records, but health and work data also could not be linked so that there were challenges in patient identification and follow-up.<sup>36</sup>

### **Strengths and weaknesses**

A strength of the WAVE trial is the multimethod approach combining a randomised trial design to explore the potential benefit of adding an early VA intervention to usual primary care, with exploration of potential cost benefits, a qualitative exploration of experiences of delivery and receipt of the VA intervention (reported separately) and a discourse analysis of the VSW/participant consultations.<sup>37</sup> The inclusion of a health economic evaluation provides valuable insights into the potential for VA interventions such as this to be cost-effective, crucial for informing policy and practice. A further strength is that the VA intervention and associated training package have been developed and could be used in a future trial in a health care or alternative setting, such as the workplace.

The key weakness was the challenged recruitment, in part due to the COVID-19 pandemic and subsequent changes to work and to primary care. In addition, despite being invited to take part in the trial, just 3.7% of people took up the invitation. Our approach to identification and invitation, the VA intervention and all patient-facing materials were developed with our PPIE group, and our qualitative data analyses found these were acceptable, although it may be that the burden of questionnaire completion affected recruitment. Talking about work and disclosing the impact of health on work is a sensitive topic for people. Concerns about job security or access to state benefits may contribute to a reluctance to participate in research that people feel could jeopardise either of these safety nets, and there was limited engagement with employers and healthcare professionals in this trial, suggesting that people were not happy to talk more widely about their health and work.<sup>35,38</sup> In recent years, the rhetoric around work has been largely negative, and this was intensified during the COVID-19 period and was widely reported in the press.<sup>39</sup> It is also possible that presenteeism (i.e. continuing to work when unwell) may have contributed to peoples' reluctance to participate,

and it has been reported that rates of presenteeism increased during the pandemic possibly due to people self-managing their conditions, at home, without support and possibly without feeling they needed support.<sup>21</sup> There is also evidence that those classed as 'essential workers' did not want to let colleagues down by being absent from the workplace.<sup>21</sup> A further weakness is the limited data available for health economic analysis; in addition to the direct costs of sickness absence, there are likely to be indirect costs such as informal care. Estimating these costs requires assumptions around what to measure, and valuing these costs is not clear.

### **Lessons learned and implications for future research**

The need for comprehensive early access to VA is still apparent as evidenced by increasing sickness absence rates and moves to implement strategies within the UK to better support those experiencing sickness absence.<sup>31,40</sup> While the WAVE trial indicates that intervening at the early stages of absence may be beneficial, this must be considered within the context of the lessons learned throughout the trial. Future research would be of value, taking account of the limitations reported here and developing recruitment methods that are more agile for clinicians and participants.

The trial relied on the engagement of primary care clinicians, patients and employers, and the limited engagement from these groups undoubtedly contributed to low recruitment. Closer working with primary care teams, providing training and support through regular contact and maintaining the profile of the trial may support clinicians to feel confident in raising awareness of the trial with their patients, which have been demonstrated to impact on recruitment.<sup>41</sup> There are also wider issues that need to be addressed to support research undertaken in primary care, which focus on the creation of a research infrastructure and culture to better support trial recruitment.<sup>42</sup> There is a need to ensure that recruitment methods are agile to address the changes seen in primary care not just during the pandemic but also as primary care services change over time. Strategies to increase recruitment suggest open trials (where participants are not blinded to the intervention nor is information about the trial withheld from them) and telephone reminders can increase recruitment rates,<sup>43</sup> and these both strategies were used in the WAVE trial. Ensuring good PPIE is key to ensure that research is relatable to patients and meets their needs.<sup>44</sup> The WAVE trial included PPIE throughout development and delivery, ensuring that potential participants' needs around trial engagement were considered throughout. There is mixed evidence as to whether PPIE members can more actively

support recruitment activity through directly recruiting to trials, although this is not a strategy that was employed in WAVE.<sup>43,45</sup> A further strategy for engagement with patients is to provide compensation for time, which has been demonstrated to be effective in increasing recruitment rates;<sup>46</sup> although not utilised in the current trial, it could be a key strategy in future trials. Work is a sensitive topic for many people, and the work-focused randomised trials attempted to date evidence that recruitment is particularly challenging.<sup>11,35</sup> Recent work exploring recruitment challenges in trials has led to the development of the QuinteT Recruitment Intervention Two (QRI-Two). QRI-Two aims to support the identification of 'hidden' challenges to recruitment using qualitative and quantitative methods to triangulate information (from recruitment screening logs, examination of trial documentation, interviews with the TMG and audio recordings of recruitment in the clinical setting) identifying challenges and developing nuanced strategies to address these.<sup>41,47</sup> While methods such as the QRI-Two are likely to be time-intensive and require teams to collect additional data around recruitment, they may be of benefit in optimising recruitment.<sup>48</sup> Lastly, it would be of value to explore the potential of delivering VA in settings other than general practice, for example other healthcare services, community settings<sup>11,49</sup> and the workplace.<sup>50</sup>

### Equality, diversity and inclusion

The trial was designed to include participants regardless of age, sex, gender, socioeconomic status or ethnicity, all of which impact on challenges in managing health and work. While the trial recruited a range of participants from different socioeconomic backgrounds [measured via Index of Multiple Deprivation (IMD)], the majority (74.6%) identified themselves as White, with 6.2% describing themselves as from other ethnicities and almost one-fifth (19.2%) declining to answer the question. This indicates that recruitment did not reach a diverse population in terms of ethnicity, and further work is required to explore the reasons around this and how research supporting people to work with health conditions can be better developed to support these groups.

### Conclusion

Our exploratory analyses of the discontinued WAVE trial suggest potential benefits of adding early, brief VA to usual primary care, to reduce work absence, improve a range of outcomes and reduce work productivity losses. Lessons learned include the need to work more closely with primary care teams and potential participants to develop agile approaches for recruitment, understanding the sensitive nature of the topic and building this into

proposed recruitment projections and lastly considering other settings for the delivery of VA. A fully powered RCT adding VA to usual primary care for adults being given fit notes still needs to be conducted, but it would require considerable changes to recruitment approaches.

### Additional information

#### CRedit contribution statement

**Gwenllian Wynne-Jones** (<https://orcid.org/0000-0002-0283-6632>): Conceptualisation (lead), Funding acquisition (lead), Methodology (equal), Project administration (equal), Supervision (lead), Visualisation (lead), Writing – original draft (lead), Writing – reviewing and editing (lead).

**Martyn Lewis** (<https://orcid.org/0000-0001-5290-7833>): Funding acquisition (equal), Methodology (lead), Supervision (lead), Data curation (lead), Formal analysis (lead), Writing – reviewing and editing (equal).

**Gail Sowden** (<https://orcid.org/0000-0003-0765-0551>): Funding acquisition (equal), Methodology (lead), Project administration (equal), Supervision (lead), Writing – reviewing and editing (equal).

**Ira Madan** (<https://orcid.org/0000-0003-2200-7329>): Conceptualisation (equal), Funding acquisition (equal), Methodology (lead), Project administration (equal), Supervision (lead), Writing – reviewing and editing (equal).

**Karen Walker-Bone** (<https://orcid.org/0000-0002-5992-1459>): Conceptualisation (equal), Funding acquisition (equal), Methodology (lead), Project administration (equal), Supervision (lead), Writing – reviewing and editing (equal).

**Carolyn A Chew-Graham** (<https://orcid.org/0000-0002-9722-9981>): Funding acquisition (equal), Methodology (lead), Project administration (equal), Supervision (lead), Writing – reviewing and editing (equal).

**Kieran Bromley** (<https://orcid.org/0000-0002-4129-2519>): Data curation (lead), Formal analysis (equal), Visualisation (equal), Writing – reviewing and editing (equal).

**Sue Jowett** (<https://orcid.org/0000-0001-8936-3745>): Funding acquisition (equal), Data curation (lead), Formal analysis (lead), Visualisation (equal), Writing – reviewing and editing (equal).

**Vaughan Parsons** (<https://orcid.org/0000-0003-0523-3770>): Funding acquisition (equal), Methodology (equal), Project administration (equal), Investigation (equal), Writing – reviewing and editing (equal).

**Gemma Mansell** (<https://orcid.org/0000-0002-5479-2678>): Funding acquisition (equal), Formal analysis (lead), Visualisation (equal), Writing – reviewing and editing (equal).

**Kendra Cooke:** Project administration (lead), Investigation (equal), Supervision (equal), Writing – reviewing and editing (equal).

**Benjamin Saunders** (<https://orcid.org/0000-0002-0856-1596>): Funding acquisition (equal), Methodology (equal), Project administration (equal), Investigation (lead), Data curation (lead), Formal analysis (lead), Supervision (equal), Writing – reviewing and editing (equal).

**Rosie Harrison** (<https://orcid.org/0000-0003-2292-5947>): Project administration (equal), Investigation (equal), Data curation (equal), Formal analysis (equal), Visualisation (equal), Writing – reviewing and editing (equal).

**Sarah A Lawton** (<https://orcid.org/0000-0002-8909-2057>): Funding acquisition (equal), Project administration (lead), Investigation (equal), Supervision (equal), Visualisation (equal), Writing – reviewing and editing (equal).

**Simon Wathall** (<https://orcid.org/0000-0002-7107-5785>): Methodology (equal), Project administration (equal), Software (lead), Writing – reviewing and editing (equal).

**John Pemberton:** Conceptualisation (equal), Funding acquisition (equal), Project administration (equal), Writing – reviewing and editing (equal).

**Julia Hammond:** Project administration (equal), Writing – reviewing and editing (equal).

**Cyrus Cooper** (<https://orcid.org/0000-0003-3510-0709>): Conceptualisation (equal), Funding acquisition (equal).

**Nadine E Foster** (<https://orcid.org/0000-0003-4429-9756>): Conceptualisation (lead), Funding acquisition (lead), Methodology (lead), Project administration (equal), Supervision (lead), Visualisation (lead), Writing – original draft (equal), Writing – reviewing and editing (equal).

## Acknowledgements

The team would like to thank the participants, the vocational support workers, the general practices and the NIHR RRDNs who supported this trial. The team would also like to thank all those who contributed to the PPIE Group from the initial development stages to completion, in particular JP who led the PPIE throughout.

## Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it is important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: <https://understandingpatientdata.org.uk/data-citation>.

## Data-sharing statement

All data are available on request, following Keele University School of Medicine data request process, by contacting the corresponding author and [medicine.datasharing@keele.ac.uk](mailto:medicine.datasharing@keele.ac.uk).

## Ethics statement

Ethical approval was granted by National Research Ethics Service (NRES) Committee West of Scotland Research Ethics Committee (REC) 5 September 2020 (REC reference: 20/WS/0127).

## Information governance statement

Keele University is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, Keele University is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: Information governance – Keele University and [dpo@keele.ac.uk](mailto:dpo@keele.ac.uk).

## Disclosure of interests

**Full disclosure of interests:** Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at <https://doi.org/10.3310/SVEG8456>.

**Primary conflicts of interest:** Gwennlian Wynne-Jones holds a contract with the National Institute for Health Research West Midlands Regional Research Delivery Network.

Ira Madan has been a member of the National Institute for Health Research Health Technology Assessment Funding Committee, 2015–21.

Carolyn A Chew-Graham is part funded by West Midlands Applied Research Collaboration.

Sue Jowett has been a member of the National Institute for Health Research Health Technology Assessment Funding Committee, 2016–20.

Nadine E Foster is funded through an Australian National Health and Medical Research Council Investigator Grant (ID: 2018182) and has also participated in the National Institute for Health Research Funding Committees up to 2021.

### Department of Health and Social Care disclaimer

This publication presents independent research commissioned by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, MRC, NIHR Coordinating Centre, the Health Technology Assessment programme or the Department of Health and Social Care.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

### Publication

The protocol is published as: Wynne-Jones G, Lewis M, Sowden G, Walker-Bone K, Ca CG, Bromley K, *et al.* Protocol for the Work And Vocational advice (WAVE) randomised controlled trial testing the addition of vocational advice to usual primary care (Clinical Trials: NCT04543097). <https://doi.org/10.1101/2024.09.11.24313466>

### Trial registration

This trial is registered with Clinical Trials: NCT04543097.

### Funding

This article presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number 17/94/49.

This article reports on one component of the research award *Work And Vocational advice (WAVE) in primary care: a randomised controlled trial*. For other articles from this thread and for more information about this research, please view the award page ([www.fundingawards.nihr.ac.uk/award/17/94/49](http://www.fundingawards.nihr.ac.uk/award/17/94/49)).

### About this article

The contractual start date for this research was in May 2019. This article began editorial review in February 2025 and was accepted for publication in August 2025. The authors have been wholly

responsible for all data collection, analysis and interpretation, and for writing up their work. The Health Technology Assessment editors and publisher have tried to ensure the accuracy of the authors' article and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

### Copyright

Copyright © 2026 Wynne-Jones *et al.* This work was produced by Wynne-Jones *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This is an Open Access publication distributed under the terms of the Creative Commons Attribution CC BY 4.0 licence, which permits unrestricted use, distribution, reproduction and adaptation in any medium and for any purpose provided that it is properly attributed. See: <https://creativecommons.org/licenses/by/4.0/>. For attribution the title, original author(s), the publication source – NIHR Journals Library, and the DOI of the publication must be cited.

### Disclaimer

Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

### List of abbreviations

DMC	Data Monitoring Committee
EMR	electronic medical record
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
HRQOL	health-related quality of life
IRR	incidence rate ratio
MCS	mental component score
MSK	musculoskeletal
OR	odds ratio
PCS	physical component score
PPIE	patient and public involvement and engagement
QRI-TWO	QuinteT Recruitment Intervention Two

RCT	randomised controlled trial
RRDN	Regional Research Delivery Network
RTW	return to work
SF-12	Short Form questionnaire-12 items
SWAP	Study of Work And Pain
TMG	Trial Management Group
TSC	Trial Steering Committee
VA	vocational advice
VSW	Vocational Support Worker
WAVE	Work And Vocational advice
WPAI	Work Productivity and Activity Impairment

## References

- Black C. *Working for a Healthier Tomorrow*. London: The Stationery Office; 2008.
- Department for Work and Pensions. *Employee Research Summary*. 2023. URL: [www.gov.uk/government/publications/employee-research-phase-1-and-2/employee-research-summary](http://www.gov.uk/government/publications/employee-research-phase-1-and-2/employee-research-summary) (accessed 8 October 2024).
- FSB. *UK Small Business Statistics*. URL: [www.fsb.org.uk/uk-small-business-statistics.html](http://www.fsb.org.uk/uk-small-business-statistics.html) (accessed 8 October 2024).
- OSHWiki | European Agency for Safety and Health at Work. *Rehabilitation and Return-to-Work Policies and Systems in European Countries*. 2022. URL: <https://oshwiki.osha.europa.eu/en/themes/rehabilitation-and-return-work-policies-and-systems-european-countries> (accessed 30 October 2024).
- Department for Work and Pensions. *Understanding the Journeys from Work to Employment and Support Allowance (ESA)*. 2015. URL: [www.gov.uk/government/publications/understanding-the-journeys-from-work-to-employment-and-support-allowance](http://www.gov.uk/government/publications/understanding-the-journeys-from-work-to-employment-and-support-allowance) (accessed 8 October 2024).
- Department for Work and Pensions. *Fit Note*. 2024. URL: [www.gov.uk/government/collections/fit-note](http://www.gov.uk/government/collections/fit-note) (accessed 8 October 2024).
- Bartys S, Edmondson A, Burton K, Parker C, Martin R. *Work Conversations in Healthcare: How, Where, When and by Whom?* London; 2019. URL: [https://assets.publishing.service.gov.uk/media/5d8399ace5274a2038154464/Work\\_Conversations\\_in\\_Healthcare\\_How\\_where\\_when\\_and\\_by\\_whom.pdf](https://assets.publishing.service.gov.uk/media/5d8399ace5274a2038154464/Work_Conversations_in_Healthcare_How_where_when_and_by_whom.pdf) (accessed 8 October 2024).
- Harrison S, Dorrington S, Parsons V, Shah SGS, Madan I. The quality of e-fit notes issued in secondary care. *Occup Med* 2020;**70**:394–9.
- Wynne-Jones G, Chew-Graham C. Why GPs must not lose their role in supporting people back to work. *Br J Gen Pract* 2022;**72**:174.
- Wynne-Jones G, Artus M, Bishop A, Lawton SA, Lewis M, Jowett S, *et al.*; SWAP Study Team. Effectiveness and costs of a vocational advice service to improve work outcomes in patients with musculoskeletal pain in primary care: a cluster randomised trial (SWAP trial ISRCTN 52269669). *Pain* 2018;**159**:128–38.
- Aanesen F, Grotle M, Rysstad TL, Tveter AT, Tingulstad A, Løchting I, *et al.* Effectiveness of adding motivational interviewing or a stratified vocational advice intervention to usual case management on return to work for people with musculoskeletal disorders: the MI-NAV randomised controlled trial. *Occup Environ Med* 2022;**80**:42–50.
- Linton SJ, Boersma K, Traczyk M, Shaw W, Nicholas M. Early workplace communication and problem solving to prevent back disability: results of a randomized controlled trial among high-risk workers and their supervisors. *J Occup Rehabil* 2016;**26**:150–9.
- Nicholas MK, Costa DSJ, Linton SJ, Main CJ, Shaw WS, Pearce G, *et al.* Implementation of early intervention protocol in Australia for 'high risk' injured workers is associated with fewer lost work days over 2 years than usual (stepped) care. *J Occup Rehabil* 2020;**30**:93–104.
- Lambeek LC, Van Mechelen W, Knol DL, Loisel P, Anema JR. Randomised controlled trial of integrated care to reduce disability from chronic low back pain in working and private life. *Br Med J* 2010;**340**:1035.
- Linton SJ, Katja B, Traczyk M, Shaw W, Nicholas M. Early workplace communication and problem solving to prevent back disability: results of a randomized controlled trial among high-risk workers and their supervisors. *J Occup Rehabil* 2015;**26**:150–9.
- Orkin AM, Gill PJ, Ghersi D, Campbell L, Sugarman J, Emsley R, *et al.*; CONSERVE Group. Guidelines for reporting trial protocols and completed trials modified due to the COVID-19 pandemic and other extenuating circumstances: the CONSERVE 2021 statement. *JAMA* 2021;**326**:257–65.

17. Mahase E. Vaccinating the UK: how the COVID vaccine was approved, and other questions answered. *Br Med J (Clinical Research Ed.)* 2020;**371**:m4759.
18. The Health Foundation. *Use of Primary Care During the COVID-19 Pandemic*. 2020. URL: [www.health.org.uk/news-and-comment/charts-and-infographics/use-of-primary-care-during-the-covid-19-pandemic](http://www.health.org.uk/news-and-comment/charts-and-infographics/use-of-primary-care-during-the-covid-19-pandemic) (accessed 2 October 2024).
19. Department for Work and Pensions. *LA Welfare Direct lite 12/2021*. 2021. URL: [www.gov.uk/government/publications/la-welfare-direct-bulletins-2021/la-welfare-direct-lite-122021](http://www.gov.uk/government/publications/la-welfare-direct-bulletins-2021/la-welfare-direct-lite-122021) (accessed 7 October 2024).
20. HM Treasury. *Furlough Scheme Extended and Further Economic Support Announced*. 2020. URL: [www.gov.uk/government/news/furlough-scheme-extended-and-further-economic-support-announced](http://www.gov.uk/government/news/furlough-scheme-extended-and-further-economic-support-announced) (accessed 2 October 2024).
21. Kinman G, Grant C. Presenteeism during the COVID-19 pandemic: risks and solutions. *Occup Med* 2021;**71**:243–4.
22. Wynne-Jones G, Lewis M, Sowden G, Walker-Bone K, Ca CG, Bromley K, *et al*. Protocol for the Work And Vocational advice (WAVE) randomised controlled trial testing the addition of vocational advice to usual primary care (Clinical Trials: NCT04543097). *MedRxiv* 2024. <https://doi.org/10.1101/2024.09.11.24313466>
23. Young AE, Viikari-Juntura E, Boot CRL, Chan C, de Porras DGR, Linton SJ, *et al*. Workplace outcomes in work-disability prevention research: a review with recommendations for future research. *J Occup Rehabil* 2016;**26**:434–47.
24. Office for National Statistics. *SOC 2020*. 2023. URL: [www.ons.gov.uk/methodology/classificationsand-standards/standardoccupationalclassificationsoc/soc2020](http://www.ons.gov.uk/methodology/classificationsand-standards/standardoccupationalclassificationsoc/soc2020) (accessed 14 October 2024).
25. Office for National Statistics. *Earnings and Hours Worked, All Employees: ASHE Table 1*. URL: [www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/allemployee-sashtable1](http://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/allemployee-sashtable1) (accessed 14 October 2024).
26. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *Pharmacoecon* 1993;**4**: 353–65.
27. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;**20**:1727–36.
28. Ware JE, Kosinski M, Keller SD. A 12-item short-form health survey: construction of scales and preliminary tests of reliability and validity. *Med Care* 1996;**34**:220–33.
29. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med* 2001;**16**:606–13.
30. PSSRU. *Unit Costs of Health and Social Care*. URL: [www.pssru.ac.uk/project-pages/unit-costs/](http://www.pssru.ac.uk/project-pages/unit-costs/) (accessed 29 October 2024).
31. Department for Work and Pensions, Department of Health and Social Care. *WorkWell Prospectus: Guidance for Local System Partnerships*. 2024. URL: [www.gov.uk/government/publications/workwell/workwell-prospectus-guidance-for-local-system-partnerships](http://www.gov.uk/government/publications/workwell/workwell-prospectus-guidance-for-local-system-partnerships) (accessed 8 October 2024).
32. Department for Work and Pensions, Department of Health and Social Care. *Employment Advisers in Musculoskeletal Pathways: Prospectus*. 2024. URL: [www.gov.uk/government/publications/employment-advisers-in-musculoskeletal-pathways-application-guidance/employment-advisers-in-musculoskeletal-pathways-prospectus](http://www.gov.uk/government/publications/employment-advisers-in-musculoskeletal-pathways-application-guidance/employment-advisers-in-musculoskeletal-pathways-prospectus) (accessed 8 October 2024).
33. Department for Work and Pensions and Department of Health and Social Care. *Employment Advisers in Improving Access to Psychological Therapies: Client Research*. Department for Work and Pensions. 2022 May.
34. Parsons V, Wainwright E, Karanika-Murray M, Muiry G, Demou E. The impact of Covid-19 on research into work and health. *Occup Med* 2024;**74**:8–14.
35. Radford KA, Wright-Hughes A, Thompson E, Clarke D, Phillips J, Holmes J, *et al*. Effectiveness of early vocational rehabilitation versus usual care to support RETURN to work After stroke: a pragmatic, parallel arm multi-centre, randomised-controlled trial. *Int J Stroke* 2024;**20**:471–85.
36. Walker-Bone K, Fraser SDS, Price C, Maguire N, Cooper C, Madan I, *et al*. A pilot trial investigating the feasibility of a future randomised controlled trial of Individualised Placement and Support for people unemployed with chronic pain recruiting in primary care. *Prim Health Care Res Dev* 2022;**23**:e39.
37. Saunders B, Chew-Graham C, Sowden G, Cooke K, Walker-Bone K, Madan I, *et al*. Constructing therapeutic support and negotiating competing agendas: a discourse analysis of vocational advice provided to individuals who are absent from work due to ill-health. *Health* 2023;**28**:185–202.
38. Brouwers EPM, Joosen MCW, Van Zelst C, Van Weeghel J. To disclose or not to disclose: a multi-stakeholder focus group study on mental health

- issues in the work environment. *J Occup Rehabil* 2013;**30**:84–92.
39. BBC. *The Rise of the Anti-Work Movement*. 2022. URL: [www.bbc.com/worklife/article/20220126-the-rise-of-the-anti-work-movement](http://www.bbc.com/worklife/article/20220126-the-rise-of-the-anti-work-movement) (accessed 29 October 2024).
  40. Office for National Statistics. *Half a Million More People Are Out of the Labour Force Because of Long-Term Sickness*. 2022. URL: [www.ons.gov.uk/employmentandlabourmarket/peoplenotinwork/economicinactivity/articles/halfamillionmorepeopleareoutofthelabourforcebecauseoflongtermsickness/2022-11-10](http://www.ons.gov.uk/employmentandlabourmarket/peoplenotinwork/economicinactivity/articles/halfamillionmorepeopleareoutofthelabourforcebecauseoflongtermsickness/2022-11-10) (accessed 1 May 2024).
  41. Farrar N, Elliott D, Jepson M, Young B, Donovan JL, Conefrey C, *et al.* The role of healthcare professionals' communication in trial participation decisions: a qualitative investigation of recruitment consultations and patient interviews across three RCTs. *Trials* 2024;**25**:829.
  42. Newmarket Strategy. *Harnessing Primary Care Data for Clinical Research and Trial Recruitment*. London; 2024. URL: [https://newmarket-strategy.com/wp-content/uploads/2024/02/Harnessing\\_primary\\_data\\_for\\_clinical\\_research\\_and\\_trials\\_recruitment-EMIS-NEW-MARKET-Final.pdf](https://newmarket-strategy.com/wp-content/uploads/2024/02/Harnessing_primary_data_for_clinical_research_and_trials_recruitment-EMIS-NEW-MARKET-Final.pdf) (accessed 9 December 2024).
  43. Treweek S, Pitkethly M, Cook J, Fraser C, Mitchell E, Sullivan F, *et al.* Strategies to improve recruitment to randomised trials. *Cochrane Database Syst Rev* 2018;**2018**.
  44. UK Standards for Public Involvement. *UK Standards for Public Involvement*. URL: <https://sites.google.com/nih.ac.uk/pi-standards/home> (accessed 9 December 2024).
  45. Crocker JC, Ricci-Cabello I, Parker A, Hirst JA, Chant A, Petit-Zeman S, *et al.* Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis. *Br Med J* 2018;**363**:k4738.
  46. Parkinson B, Meacock R, Sutton M, Fichera E, Mills N, Shorter GW, *et al.* Designing and using incentives to support recruitment and retention in clinical trials: a scoping review and a checklist for design. *Trials* 2019;**20**:1–14.
  47. Donovan JL, Jepson M, Rooshenas L, Paramasivan S, Mills N, Elliott D, *et al.* Development of a new adapted QuinteT Recruitment Intervention (QRI-Two) for rapid application to RCTs underway with enrolment shortfalls – to identify previously hidden barriers and improve recruitment. *Trials* 2022;**23**:1–14.
  48. Wade J, Farrar N, Realpe AX, Donovan JL, Forsyth L, Harkness KA, *et al.*; CARE pilot trial collaboration. Addressing barriers and identifying facilitators to support informed consent and recruitment in the Cavernous malformations A Randomised Effectiveness (CARE) pilot phase trial: insights from the integrated QuinteT recruitment intervention (QRI). *EClinicalMedicine* 2024;**71**:102557.
  49. NHS Digital. *NHS Talking Therapies, for Anxiety and Depression, Annual Reports, 2022–23*. 2024. URL: <https://digital.nhs.uk/data-and-information/publications/statistical/nhs-talking-therapies-for-anxiety-and-depression-annual-reports/2022-23> (accessed 8 May 2024).
  50. van Vilsteren M, van Oostrom SH, de Vet HCW, Franche RL, Boot CRL, Anema JR. Workplace interventions to prevent work disability in workers on sick leave. *Cochrane Database Syst Rev* 2015;**2015**:CD006955.

## Appendix 1

TABLE 5 Baseline characteristics

	$N_{\text{Int}}$ , $N_{\text{Cont}}$	Usual care plus VA intervention (n = 66)	Usual care alone (n = 64)	Total (n = 130)
Age, mean (SD)	66, 64	49.30 (11.31)	48.62 (11.41)	48.97 (11.32)
<b>Sex, n (%)</b>	66, 64			
Female		47 (71.2%)	43 (67.2%)	90 (69.2%)
Male		19 (28.8%)	21 (32.8%)	40 (30.8%)
<b>Ethnicity, n (%)<sup>a</sup></b>	66, 64			
White		51 (77.3%)	46 (71.9%)	97 (74.6%)
Other		4 (6.1%)	4 (6.2%)	8 (6.2%)
Missing/not stated		11 (16.7%)	14 (21.9%)	25 (19.2%)
<b>Level of education,<sup>b</sup> n (%)</b>				
O-level/GCSE (or equivalents)	66, 64	34 (51.5%)	32 (50.0%)	66 (50.8%)
A-levels (or equivalents)	66, 64	23 (34.8%)	20 (31.2%)	43 (33.1%)
Vocational training certificate(s)	66, 64	36 (54.5%)	40 (62.5%)	76 (58.5%)
Higher professional qualifications (degree and so on)	66, 64	31 (47.0%)	27 (42.2%)	58 (44.6%)
<b>Main health condition causing time off work, n (%)</b>	66, 64			
MH		23 (34.8%)	25 (39.1%)	48 (36.9%)
MSK		22 (33.3%)	22 (34.4%)	44 (33.8%)
None and other <sup>c</sup>		21 (31.8%)	17 (26.6%)	38 (29.2%)
Total days of absence in past 6 months, mean (SD)	65, 63	34.65 (33.49)	33.73 (33.80)	34.20 (33.51)
SF-12 PCS, mean (SD)	64, 63	33.69 (13.21)	33.22 (11.20)	33.46 (12.21)
SF-12 MCS, mean (SD)	64, 63	35.25 (14.66)	34.47 (11.50)	34.86 (13.14)
<b>Depression (PHQ-8), mean (SD)</b>	65, 64	12.67 (6.44)	12.25 (6.24)	12.46 (6.32)
None		10 (15.4%)	8 (12.5%)	18 (14.0%)
Mild		12 (18.5%)	15 (23.4%)	27 (20.9%)
Moderate		13 (20.0%)	16 (25.0%)	29 (22.5%)

continued

**TABLE 5** Baseline characteristics (continued)

	$N_{Int}$ , $N_{Cont}$	Usual care plus VA intervention (n = 66)	Usual care alone (n = 64)	Total (n = 130)
Moderate-severe		20 (20.8%)	14 (21.9%)	34 (26.4%)
Severe		10 (15.4%)	11 (17.2%)	21 (16.3%)
Anxiety (GAD-7), mean (SD)	65, 63	10.20 (6.86)	9.89 (6.01)	10.05 (6.43)
Attitudes and beliefs to work, mean (SD)	63, 63	38.00 (6.27)	38.27 (7.21)	38.13 (6.73)
RTW-SE, mean (SD)	63, 63	5.27 (2.19)	4.79 (2.42)	5.03 (2.31)
<b>Physical activity level (GPPAQ3), n (%)</b>	60, 63			
Inactive		15 (25.0%)	25 (39.7%)	40 (32.5%)
Moderately inactive		15 (25.0%)	12 (19.0%)	27 (22.0%)
Moderately active		14 (23.3%)	13 (20.6%)	27 (22.0%)
Active		16 (26.7%)	13 (20.6%)	29 (23.6%)
<b>Use and content of other services providing VA, n (%)</b>				
Vocational advisor	56, 56	3 (5.4%)	6 (10.7%)	9 (8.0%)
GP	65, 63	47 (72.3%)	52 (82.5%)	99 (77.3%)
My organisation's occ. health department	58, 57	18 (31.0%)	16 (28.1%)	34 (29.6%)
Practice nurse	56, 56	7 (12.5%)	11 (19.6%)	18 (16.1%)
Physiotherapist	59, 58	16 (27.1%)	15 (25.9%)	31 (26.5%)
Other <sup>d</sup>	50, 46	25 (50%)	24 (52.2%)	49 (51.0%)
<b>Working hours, n (%)</b>				
Full-time (≥ 35 hours per week)		41 (63.1%)	49 (79.0%)	90 (70.9%)
Part-time (< 35 hours per week)		24 (36.9%)	13 (21.0%)	37 (29.1%)
<b>Paid hours of work per week, mean (SD)</b>				
Full-time	41, 49	39.93 (3.68)	37.29 (3.86)	38.03 (3.85)
Part-time	23, 13	23.70 (6.44)	25.38 (6.53)	24.31 (6.43)
<b>Work characteristics, n (%)</b>				
Kneeling/squatting for > 1 hour per day	66, 64	12 (18.2%)	15 (23.4%)	27 (20.8%)
Climbing a ladder	66, 64	4 (6.1%)	10 (15.6%)	14 (10.8%)
Climbing up/down stairs > 30 times per day	66, 64	22 (33.3%)	24 (37.5%)	46 (35.4%)

	$N_{Int}$ , $N_{Cont}$	Usual care plus VA intervention (n = 66)	Usual care alone (n = 64)	Total (n = 130)
Digging or shovelling	66, 64	0 (0%)	1 (1.6%)	1 (0.8%)
Lifting weights of $\geq 10$ kg by hand	66, 63	16 (24.2%)	19 (30.2%)	35 (27.1%)
Standing/walking for most of the day	66, 64	28 (42.4%)	26 (40.6%)	54 (41.5%)
Standing/walking for > 3 hours at a time	66, 64	25 (37.9%)	24 (37.5%)	49 (37.7%)
Hard physical work that makes you hot/sweaty	66, 63	19 (28.8%)	16 (25.4%)	35 (27.1%)
<b>What is the gross total income from all sources per week? N (%)</b>	65, 64			
£0–99 (£0–5199 per year)		0 (0%)	0 (0%)	0 (0%)
£100–149 (£5200–7799 per year)		0 (0%)	1 (1.6%)	1 (0.8%)
£150–249 (£7800–12,999 per year)		1 (1.5%)	1 (1.6%)	2 (1.6%)
£250–349 (£13,000–18,199 per year)		7 (10.8%)	6 (9.4%)	13 (10.1%)
£350–449 (£18,200–23,399 per year)		10 (15.4%)	3 (4.7%)	13 (10.1%)
£450–599 (£23,400–31,199 per year)		2 (3.1%)	8 (12.5%)	10 (9.3%)
£500–£749 (£31,200–38,999 per year)		6 (9.2%)	6 (9.4%)	12 (9.3%)
$\geq$ £750 ( $\geq$ £39,000 per year)		28 (43.1%)	31 (48.4%)	59 (45.7%)
Prefer not to say		11 (16.9%)	8 (12.5%)	19 (14.7%)
<b>Support from line manager/supervisor, n (%)</b>	65, 64			
Very good/good		38 (58.5%)	33 (51.6%)	71 (55.0%)
Not a problem/slight problem, major problem		27 (41.5%)	31 (48.4%)	58 (45.0%)
<b>Pace of work, n (%)</b>	65, 64			
Very good/good		18 (27.7%)	18 (28.1%)	36 (27.9%)
Not a problem/slight problem, major problem		47 (72.3%)	46 (71.9%)	93 (72.1%)
<b>Feedback on performance, n (%)</b>	64, 64			
Very good/good		38 (59.4%)	27 (42.2%)	65 (50.8%)
Not a problem/slight problem, major problem		26 (40.6%)	37 (57.8%)	63 (49.2%)
<b>Workload, n (%)</b>	65, 64			
Very good/good		18 (27.7%)	16 (25.0%)	34 (26.4%)
Not a problem/slight problem, major problem		47 (72.3%)	48 (75.0%)	95 (73.6%)

continued

**TABLE 5** Baseline characteristics (continued)

	<i>N</i> <sub>Int</sub> <sup>a</sup> , <i>N</i> <sub>Cont</sub>	Usual care plus VA intervention (n = 66)	Usual care alone (n = 64)	Total (n = 130)
IMD rank	59, 50	21,601 (8770.6)	19,704 (8185.9)	20,731 (8521.5)
<b>IMD quintiles, n (%)</b>	59, 50			
0–19%		3 (5.1%)	3 (6.0%)	6 (5.5%)
20–39%		10 (16.9%)	11 (22.0%)	21 (19.3%)
40–59%		13 (22.0%)	14 (28.0%)	27 (24.8%)
60–79%		6 (10.2%)	8 (16.0%)	14 (12.8%)
80–100%		27 (45.8%)	14 (28.0%)	41 (37.6%)
Satisfaction with work, mean (SD)	66, 64	5.47 (2.54)	5.16 (2.92)	5.32 (2.73)
<b>How do you commute to work? N (%)</b>				
Walk	66, 64	4 (6.1%)	7 (10.9%)	11 (8.5%)
Cycle	66, 64	5 (7.6%)	2 (3.1%)	7 (5.4%)
Public transport	66, 64	10 (15.2%)	13 (20.3%)	23 (17.7%)
Car (private or shared)	66, 64	41 (62.1%)	40 (62.5%)	81 (62.3%)
N/A (e.g. work from home)	66, 64	8 (12.1%)	11 (17.2%)	19 (14.6%)
How long is your commute to work (minutes)? Mean (SD)		35.52 (24.38)	33.60 (23.99)	34.59 (24.10)
Health related quality of life (EQ-5D-5L), mean (SD)	66, 63	0.57 (0.30)	0.51 (0.30)	0.54 (0.30)

GCSE: General Certificate of Secondary Education; GP, general practitioner; GPPAQ3: General Practice Physical Activity Questionnaire 3; N/A, not applicable; OH: Occupational Health. Attitudes and beliefs to work (0–60), 0 = not impacting RTW, 60 = high impact on returning to work; EQ-5D-5L (utility) (–0.59–1.00), –0.59 = worst health utility, 1.00 = best health utility; GAD-7, Generalised Anxiety Disorder-7 (0–21), 0 = no anxiety, 21 = severe anxiety; IMD, 1 = most deprived, 32,844 = least deprived; *N*<sub>Cont</sub><sup>b</sup>, Number in usual care alone; *N*<sub>Int</sub><sup>c</sup>, number in VA intervention plus usual care; PHQ-8, Patient Health Questionnaire depression scale (0–24), 0 = no depression, 24 = severe depression; RTW-SE, RTW self-efficacy (19 items) (1–10); 1 = low self-efficacy, 10 = high self-efficacy; SF-12 MCS, (0–100), 0 = worst MH score, 100 = best MH score; SF-12 PCS, (0–100), 0 = worst physical health score, 100 = best physical health score.

Ethnicity: other subgroup includes any response indicating a non-white ethnicity.

a These data were collected via Medical Records. Information was not available from two (n = 20 participants; Int = 7, Cont = 13) sites and was listed as missing. Some data from sites providing information were also missing.

b The participant could provide multiple responses.

c None and other group includes those who did not report a main health condition and all those who reported non-MH or MSK condition.

d Other includes accident and emergency, OH, bereavement counsellor, Samaritans, cognitive-behavioural therapy psychotherapist, chiropractor, clinical psychologist, hospital consultant/nurse, orthopaedic surgeon, counsellor, dentist, dermatologist, employee assistance program, I-talk, MH nurses/team, cancer trust, Unison reps, well-being services.

## Appendix 2

TABLE 6 Pre-specified exploratory subgroup analyses

Outcome	$N_{Int}$ , $N_{Cont}$	VA intervention (n = 66)	Usual care alone (n = 64)	Total (n = 130)	Time off work (days)
<b>Main health condition resulting in time off work</b>	66, 64				
MH		23 (34.8%)	25 (39.1%)	48 (36.9%)	n = 46, mean = 34.78 (SD = 51.48); median = 10 (IQR = 6.14–96)
MSK		22 (33.3%)	22 (34.4%)	44 (33.8%)	n = 43, mean = 39.85 (SD = 54.68); median = 14 (IQR = 0.18–30)
None or other		21 (31.8%)	17 (26.6%)	38 (29.2%)	n = 36, mean = 47.56 (SD = 53.94); median = 18 (IQR = 0.50–51.29)
<b>Previous time off work in the past 6 months</b>	65, 63				
Short-term ( $\leq 4$ weeks)		40 (61.5%)	35 (55.6%)	75 (58.6%)	n = 72, mean = 27.84 (SD = 43.80); median = 8.57 (IQR = 0–30.5)
Long-term ( $> 4$ weeks)		25 (38.5%)	28 (44.4%)	53 (41.4%)	n = 52, mean = 55.78 (SD = 60.03); median = 26 (IQR = 6.14–113.57)

The reference group for each model are: main health condition, none or other; previous time off work, short-term ( $\leq 4$  weeks);  $N_{Int}$ , number in VA intervention arm;  $N_{Cont}$ , number in usual care alone arm.

Interaction effects: MH  $\times$  usual care alone arm = 1.17 (0.500, 2.495); MSK  $\times$  usual care alone arm = 0.647 (0.287, 1.455); long-term  $\times$  usual care alone arm = 0.967 (0.505, 1.852).

## Appendix 3

TABLE 7 Sensitivity analyses investigating individual components of the intervention by reporting time off work for each level of the intervention

Level of intervention delivered	Time off work over 6 months
Step 0	n = 7, <sup>a</sup> mean = 33.55 (SD = 49.40) Median = 10.71 (IQR = 5.36–36.71)
Step 1	n = 8, mean = 28.66 (SD = 43.93) Median = 12.64 (IQR = 0–33.5)
Step 2	n = 35, <sup>a</sup> mean = 43.47 (SD = 49.00) Median = 28 (IQR = 1.5–56)
Step 3	N/A

WRAP, WAVE Return to work Assessment Plan.

a This is 1 < reported in the WRAP (CRF02) table as one participant failed to provide any time to return work data.

Step 0 = participant declined to take up the intervention; step 1 = phone call to discuss obstacles to RTW and develop RTW plan; step 2 = further call, F2F/video-conf to review, amend and support the RTW plan; step 3 = contact made with workplace to agree and implement RTW plan.

## Appendix 4

TABLE 8 Secondary outcome measures at 6 weeks

Secondary outcomes	N <sub>A</sub> , N <sub>B</sub>	Arm A (n = 49)	Arm B (n = 43)	Total (n = 92)	Mean difference/OR (95% CI)	Mean difference/OR (90% CI)	Mean difference/OR (80% CI)
COVID-related work absence, n (%)	50, 48	4 (8.0%)	2 (4.2%)	6 (6.1%)	0.471 (0.055 to 29.17)	0.471 (0.081 to 2.180)	0.471 (0.124 to 1.561)
<b>Work interference (WPAI), mean (SD)</b>							
Absenteeism	41, 39	39.37 (47.05)	49.68 (46.77)	44.40 (46.9)	9.907 (-12.294 to 32.108)	9.907 (-8.652 to 28.467)	9.907 (-4.501 to 24.315)
Presenteeism	35, 27	44.29 (29.03)	47.78 (27.08)	45.81 (28.03)	2.845 (-12.289 to 17.979)	2.845 (-9.791 to 15.481)	2.845 (-6.953 to 12.643)
Work productivity loss	31, 25	46.27 (32.22)	54.90 (31.64)	50.12 (31.96)	4.645 (-13.248 to 22.537)	4.645 (-10.284 to 19.574)	4.645 (-6.924 to 16.124)
Activity impairment	49, 43	46.12 (25.07)	53.02 (31.44)	49.35 (28.28)	6.925 (-4.442 to 18.291)	6.925 (-2.583 to 16.432)	6.925 (-0.460 to 14.209)
Work performance (SIPQ), mean (SD)	47, 48	5.74 (3.32)	5.88 (3.13)	5.81 (3.21)	0.090 (-1.301 to 1.481)	0.090 (-1.074 to 1.254)	0.090 (-0.814 to 0.994)
SF-12 PCS, mean (SD)	48, 41	38.70 (12.70)	36.32 (12.00)	37.61 (12.37)	-2.181 (-5.970 to 1.608)	-2.181 (-5.350 to 0.987)	-2.181 (-4.641 to 0.279)
SF-12 MCS, mean (SD)	48, 41	39.43 (12.62)	38.76 (11.55)	39.12 (12.08)	0.049 (-3.955 to 4.053)	0.049 (-3.299 to 3.397)	0.049 (-2.551 to 2.649)
Depression [PHQ-8], mean (SD)	49, 43	8.78 (5.91)	9.33 (6.12)	9.04 (5.98)	0.464 (-1.394 to 2.322)	0.464 (-1.090 to 2.018)	0.464 (-0.743 to 1.671)
<b>Depression [PHQ-8] categorised, n (%)</b>					1.070 (0.469 to 2.439)	1.070 (0.536 to 2.135)	1.070 (0.624 to 1.832)
None		13 (26.5%)	10 (22.2%)	23 (24.5%)			
Mild		14 (28.6%)	13 (28.9%)	27 (28.7%)			
Moderate		10 (20.4%)	11 (24.4%)	21 (22.3%)			
Moderate-severe		11 (22.4%)	8 (17.8%)	19 (20.2%)			
Severe		1 (2.0%)	3 (6.7%)	4 (4.3%)			
Anxiety [GAD-7], mean (SD)	49, 42	7.53 (6.06)	7.76 (6.12)	7.64 (6.08)	0.205 (-1.683 to 2.093)	0.205 (-1.374 to 1.784)	0.205 (-1.021 to 1.431)
Attitudes and beliefs to work, mean (SD)	43, 41	38.70 (7.41)	38.51 (6.77)	38.61 (7.06)	-1.112 (-3.779 to 1.556)	-1.112 (-3.342 to 1.119)	-1.112 (-2.843 to 0.620)
RTW-SE, mean (SD)	48, 42	5.62 (2.23)	5.55 (2.29)	5.58 (2.25)	0.005 (-0.951 to 0.961)	0.005 (-0.795 to 0.805)	0.005 (-0.616 to 0.626)

Secondary outcomes	$N_A, N_B$	Arm A (n = 49)	Arm B (n = 43)	Total (n = 92)	Mean difference/OR (95% CI)	Mean difference/OR (90% CI)	Mean difference/OR (80% CI)
<b>Physical activity level [GPPAQ3], n (%)</b>	46, 42				0.672 (0.271 to 1.662)	0.672 (0.314 to 1.436)	0.672 (0.372 to 1.214)
Inactive		15 (32.6%)	15 (35.7%)	30 (34.1%)			
Moderately inactive		7 (15.2%)	11 (26.2%)	18 (20.5%)			
Moderately active		11 (23.9%)	9 (21.4%)	20 (22.7%)			
Active		13 (28.3%)	7 (16.7%)	20 (22.7%)			
<b>Use and content of other services providing VA, n (%)</b>							
Vocational advisor	43, 38	15 (34.9%)	2 (5.3%)	17 (21.0%)			
GP	44, 43	19 (43.2%)	18 (41.9%)	37 (42.5%)	0.885 (0.350 to 2.216)	0.885 (0.407 to 1.910)	0.885 (0.484 to 1.611)
My organisation's occ. Health department	44, 40	17 (38.6%)	10 (25.0%)	27 (32.1%)	0.424 (0.135 to 1.234)	0.424 (0.164 to 1.042)	<b>0.424 (0.203 to 0.857)</b>
Practice nurse	42, 40	3 (7.1%)	5 (12.5%)	8 (9.8%)	2.963 (0.550 to 23.276)	2.963 (0.716 to 15.901)	2.963 (0.973 to 10.549)
Physiotherapist	41, 39	7 (17.1%)	7 (17.9%)	14 (17.5%)	0.814 (0.172 to 3.620)	0.814 (0.223 to 2.840)	0.814 (0.300 to 2.152)
Other	39, 39	14 (35.9%)	12 (30.8%)	26 (33.3%)	0.750 (0.203 to 2.665)	0.750 (0.252 to 2.170)	0.750 (0.323 to 1.715)
<b>Working hours, n (%)</b>	41, 41				0.556 (0.154 to 1.936)	0.556 (0.191 to 1.580)	0.556 (0.243 to 1.253)
Full time ( $\geq 35$ hours per week)		23 (56.1%)	30 (73.2%)	53 (64.6%)			
Part time (< 35 hours per week)		18 (43.9%)	11 (26.8%)	29 (35.4%)			
<b>Work characteristics, n (%)</b>							
Kneeling/squatting for > 1 hour per day	44, 43	10 (22.7%)	6 (14.0%)	16 (18.4%)	0.304 (0.041 to 1.399)	0.304 (0.060 to 1.110)	<b>0.304 (0.090 to 0.846)</b>
Climbing a ladder	44, 43	5 (11.4%)	6 (14.0%)	11 (12.6%)	0.787 (0.091 to 5.517)	0.787 (0.134 to 3.992)	0.787 (0.205 to 2.774)
Climbing up/down stairs > 30 times per day	44, 43	5 (11.4%)	4 (9.3%)	9 (10.3%)	0.722 (0.142 to 3.370)	0.722 (0.188 to 2.620)	0.722 (0.256 to 1.967)
Digging or shovelling	44, 43	1 (2.3%)	0 (0.0%)	1 (1.1%)	-	-	-
Lifting weights of $\geq 10$ kg by hand	44, 43	8 (18.2%)	10 (23.3%)	18 (20.7%)	2.468 (0.609 to 11.296)	2.468 (0.762 to 8.716)	2.468 (0.985 to 6.516)
Standing/walking for most of the day	44, 43	20 (45.5%)	19 (44.2%)	39 (44.8%)	0.873 (0.156 to 4.787)	0.873 (0.208 to 3.605)	0.873 (0.289 to 2.617)

continued

**TABLE 8** Secondary outcome measures at 6 weeks (continued)

Secondary outcomes	N <sub>A</sub> , N <sub>B</sub>	Arm A (n = 49)	Arm B (n = 43)	Total (n = 92)	Mean difference/OR (95% CI)	Mean difference/OR (90% CI)	Mean difference/OR (80% CI)
Standing/walking for > 3 hours at a time	44, 43	15 (34.1%)	17 (39.5%)	32 (36.8%)	1.339 (0.365 to 4.930)	1.339 (0.452 to 3.976)	1.339 (0.577 to 3.113)
Hard physical work that makes you hot/sweaty	44, 43	12 (27.3%)	11 (25.6%)	23 (26.4%)	1.681 (0.554 to 5.445)	1.681 (0.661 to 4.474)	1.681 (0.811 to 3.582)
Satisfaction with work, mean (SD)	44, 43	5.50 (2.82)	5.47 (2.83)	5.48 (2.81)	0.299 (-0.663 to 1.261)	0.299 (-0.506 to 1.103)	0.299 (-0.326 to 0.924)
Health related quality of life (EQ-5D-5L), mean (SD)	49, 42	0.71 (0.22)	0.56 (0.30)	0.64 (0.27)	-0.080 (-0.167 to 0.007)	<b>-0.080 (-0.153 to -0.007)</b>	<b>-0.080 (-0.136 to -0.024)</b>
<b>Perceived change in health condition, n (%)</b>	50, 48				1.107 (0.516 to 2.373)	1.107 (0.584 to 2.098)	1.107 (0.673 to 1.821)
Completely recovered		0 (0.0%)	1 (2.0%)	1 (1.0%)			
Much improved		18 (36.0%)	13 (27.1%)	31 (31.6%)			
Somewhat improved		17 (34.0%)	16 (33.3%)	33 (33.7%)			
The same		7 (14.0%)	14 (29.2%)	21 (21.4%)			
Somewhat worse		6 (12.0%)	3 (6.2%)	9 (9.2%)			
Much worse		2 (4.0%)	1 (2.1%)	3 (3.1%)			

SIPQ, Single Item Presenteeism Question.

**Note**

Analyses are now adjusted for arm, region, associated baseline score (where available) and health condition resulting in time off work. The numbers in bold highlight statistically significant associations.

## Appendix 5

**TABLE 9** Secondary outcome measures at 6 months

Secondary outcomes	$N_A, N_B$	Intervention arm (n = 42)	Control arm (n = 39)	Total (n = 81)	Mean difference/OR (95% CI)	Mean difference/OR (90% CI)	Mean difference/OR (80% CI)
COVID-related work absence, n (%)	40, 39	5 (12.5%)	3 (7.7%)	8 (10.1%)	0.833 (0.143 to 4.391)	0.833 (0.194 to 3.343)	0.833 (0.272 to 2.451)
<b>Work interference (WPAI), mean (SD)</b>							
Absenteeism	33, 32	28.45 (43.69)	19.37 (39.43)	23.98 (41.58)	-8.849 (-28.436 to 10.738)	-8.849 (-25.207 to 7.508)	-8.849 (-21.536 to 3.837)
Presenteeism	30, 33	33.33 (31.44)	34.85 (34.38)	34.13 (32.76)	-0.958 (-17.394 to 15.478)	-0.958 (-14.682 to 12.766)	-0.958 (-11.600 to 9.684)
Work productivity loss	27, 28	35.86 (31.71)	40.56 (34.55)	38.25 (32.96)	2.143 (-15.566 to 19.852)	2.143 (-12.631 to 16.917)	2.143 (-9.305 to 13.591)
Activity impairment	40, 39	42.00 (37.84)	38.21 (32.51)	40.13 (35.14)	-6.247 (-22.071 to 9.577)	-6.247 (-19.475 to 6.981)	-6.247 (-16.516 to 4.021)
Work performance (SIPQ), mean (SD)	37, 39	4.30 (3.91)	4.90 (3.67)	4.61 (3.78)	0.415 (-1.311 to 2.141)	0.415 (-1.027 to 1.857)	0.415 (-0.704 to 1.534)
SF-12 PCS, mean (SD)	39, 39	39.63 (14.47)	39.90 (12.26)	39.77 (13.32)	1.840 (-3.365 to 7.045)	1.840 (-2.510 to 6.190)	1.840 (-1.536 to 5.216)
SF-12 MCS, mean (SD)	39, 39	43.70 (13.50)	40.69 (11.48)	42.19 (12.54)	-3.197 (-7.951 to 1.556)	-3.197 (-7.170 to 0.775)	-3.197 (-6.280 to -0.114)
Depression [PHQ-8], mean (SD)	40, 39	8.43 (6.43)	9.67 (6.25)	9.04 (6.33)	0.798 (-1.434 to 0.030)	0.798 (-1.068 to 2.664)	0.798 (-0.650 to 2.246)
<b>Depression [PHQ-8] categorised, n (%)</b>	40, 39				1.255 (0.521 to 3.034)	1.255 (0.601 to 2.630)	1.255 (0.707 to 2.232)
None		16 (35.6%)	8 (19.5%)	24 (27.9%)			
Mild		8 (17.8%)	16 (39.0%)	24 (27.9%)			
Moderate		12 (26.7%)	8 (19.5%)	20 (23.3%)			
Moderate-severe		7 (15.6%)	4 (9.8%)	11 (12.8%)			
Severe		2 (4.4%)	5 (12.2%)	7 (8.1%)			
Anxiety [GAD-7], mean (SD)	40, 39	6.97 (6.52)	6.67 (5.44)	6.82 (5.97)	-0.117 (-2.187 to 1.953)	-0.117 (-1.847 to 1.614)	-0.117 (-1.460 to 1.227)

continued

**TABLE 9** Secondary outcome measures at 6 months (continued)

Secondary outcomes	N <sub>A</sub> , N <sub>B</sub>	Intervention arm (n = 42)	Control arm (n = 39)	Total (n = 81)	Mean difference/OR (95% CI)	Mean difference/OR (90% CI)	Mean difference/OR (80% CI)
Attitudes and beliefs to work, mean (SD)	36, 38	36.44 (7.32)	35.95 (5.95)	36.19 (6.61)	-1.500 (-4.209 to 1.209)	-1.500 (-3.763 to 0.764)	-1.500 (-3.256 to 0.257)
RTW-SE, mean (SD)	38, 38	6.56 (2.50)	6.05 (2.69)	6.31 (2.59)	-0.371 (-1.597 to 0.856)	-0.371 (-1.396 to 0.654)	-0.371 (-1.166 to 0.425)
<b>Physical activity level [GPPAQ3], n (%)</b>	38, 39				0.671 (0.270 to 1.653)	0.671 (0.313 to 1.430)	0.671 (0.371 to 1.210)
Inactive		10 (26.3%)	12 (30.8%)	22 (28.6%)			
Moderately inactive		6 (15.8%)	9 (23.1%)	15 (19.5%)			
Moderately active		11 (28.9%)	10 (25.6%)	21 (27.3%)			
Active		11 (28.9%)	8 (20.5%)	19 (24.7%)			
<b>Use and content of other services providing VA, n (%)</b>							
Vocational advisor	39, 37	5 (12.8%)	2 (5.4%)	7 (9.2%)			
GP	39, 39	15 (38.5%)	13 (33.3%)	28 (35.9%)	0.824 (0.301 to 2.229)	0.824 (0.354 to 1.897)	0.824 (0.428 to 1.577)
My organisation's occ. health department	40, 38	10 (25.0%)	12 (31.6%)	22 (28.2%)	1.267 (0.386 to 4.257)	1.267 (0.468 to 3.485)	1.267 (0.584 to 2.776)
Practice nurse	39, 38	7 (17.9%)	6 (15.8%)	13 (16.9%)	0.684 (0.184 to 2.445)	0.684 (0.229 to 1.987)	0.684 (0.293 to 1.568)
Physiotherapist	39, 37	8 (20.5%)	6 (16.2%)	14 (18.4%)	0.563 (0.132 to 2.181)	0.563 (0.169 to 1.755)	0.563 (0.222 to 1.367)
Other	35, 36	12 (34.3%)	12 (33.3%)	24 (33.8%)	0.849 (0.231 to 3.056)	0.849 (0.287 to 2.480)	0.849 (0.366 to 1.953)
<b>Working hours, n (%)</b>	34, 35				0.384 (0.119 to 1.148)	<b>0.384 (0.145 to 0.965)</b>	<b>0.384 (0.181 to 0.789)</b>
Full-time (≥ 35 hours per week)		20 (58.8%)	27 (77.1%)	47 (68.1%)			
Part-time (< 35 hours per week)		14 (41.2%)	8 (22.9%)	22 (31.9%)			
<b>Work characteristics, n (%)</b>							
Kneeling/squatting for > 1 hour per day	40, 38	6 (15.0%)	5 (13.2%)	11 (14.1%)	0.260 (0.012 to 1.941)	0.260 (0.023 to 1.435)	0.260 (0.044 to 1.008)
Climbing a ladder	40, 37	1 (2.5%)	2 (5.4%)	3 (3.9%)	2.229 (0.205 to 49.185)	2.229 (0.306 to 26.229)	2.229 (0.478 to 13.762)
Climbing up/down stairs > 30 times per day	40, 37	3 (7.5%)	3 (8.1%)	8 (7.8%)	0.716 (0.106 to 4.559)	0.716 (0.147 to 3.337)	0.716 (0.212 to 2.353)
Digging or shovelling	40, 37	0 (0.0%)	1 (2.7%)	1 (1.3%)	-	-	-

Secondary outcomes	$N_A, N_B$	Intervention arm (n = 42)	Control arm (n = 39)	Total (n = 81)	Mean difference/OR (95% CI)	Mean difference/OR (90% CI)	Mean difference/OR (80% CI)
Lifting weights of $\geq$ 10 kg by hand	40, 38	8 (20.0%)	9 (23.7%)	17 (21.8%)	3.067 (0.515 to 26.877)	3.067 (0.681 to 18.069)	3.067 (0.941 to 11.749)
Standing/walking for most of the day	40, 38	19 (47.5%)	14 (36.8%)	33 (42.3%)	0.848 (0.161 to 4.460)	0.848 (0.213 to 3.378)	0.848 (0.291 to 2.470)
Standing/walking for > 3 hours at a time	40, 38	14 (35.0%)	14 (36.8%)	28 (35.9%)	1.168 (0.332 to 4.221)	1.168 (0.408 to 3.409)	1.168 (0.515 to 2.677)
Hard physical work that makes you hot/sweaty	40, 38	10 (25.0%)	9 (23.7%)	19 (24.4%)	0.819 (0.264 to 2.468)	0.819 (0.318 to 2.065)	0.819 (0.393 to 1.682)
Satisfaction with work, mean (SD)	39, 38	5.51 (2.52)	5.24 (3.04)	5.38 (2.78)	-0.196 (-1.326 to 0.934)	-0.196 (-1.141 to 0.748)	-0.196 (-0.929 to 0.537)
HRQoL (EQ-5D-5L), mean (SD)	39, 39	0.71 (0.30)	0.69 (0.28)	0.70 (0.29)	0.031 (-0.065 to 0.127)	0.031 (-0.49 to 0.111)	0.031 (-0.031 to 0.093)
<b>Perceived change in health condition, n (%)</b>	39, 39				1.101 (0.482 to 2.516)	1.101 (0.551 to 2.201)	1.101 (0.642 to 1.888)
Completely recovered		7 (17.9%)	4 (10.3%)	11 (14.1%)			
Much improved		12 (30.8%)	13 (33.3%)	25 (32.1%)			
Somewhat improved		8 (20.5%)	11 (28.2%)	19 (24.4%)			
The same		5 (12.8%)	8 (20.5%)	13 (16.7%)			
Somewhat worse		5 (12.8%)	3 (7.7%)	8 (10.3%)			
Much worse		2 (5.1%)	0 (0.0%)	2 (2.6%)			
<b>Note</b>							
Bold values indicate a statistically significant association.							

## Appendix 6

**TABLE 10** Testing of mediation pathways prior to running mediation analysis: *a* path (group allocation as IV; potential mediator scores at 6-week follow-up as DV)

Potential mediator (measured at 6 weeks)	<i>n</i> in each model	<i>R</i> (standardised beta)	Unstandardised beta (SE)	95% CI	90% CI	80% CI
SF-12 PCS (0–100) – higher score = better health	89	0.10	-2.39 (2.63)	-7.62 to 2.85	-6.77 to 2.00	-5.79 to 1.02
SF-12 MCS (0–100) – higher score = better health	89	0.03	-0.67 (2.58)	-5.80 to 4.47	-4.96 to 3.63	-4.00 to 2.67
Depression [PHQ-8] (0–24) – higher score = worse depression	92	0.05	0.56 (1.26)	-1.94 to 3.05	-1.53 to 2.64	-1.06 to 2.18
Anxiety [GAD-7] (0–21) – higher score = worse anxiety	91	0.02	0.23 (1.29)	-2.32 to 2.78	-1.90 to 2.37	-1.43 to 1.89
Attitudes and Beliefs scale (0–60) – higher score = higher impact on RTW	84	0.01	-0.19 (1.55)	-3.27 to 2.90	-2.77 to 2.40	-2.19 to 1.82
RTW SE (0–10) – higher score = increased RTW SE	90	0.02	-0.07 (0.48)	-1.02 to 0.88	-0.87 to 0.72	-0.69 on 0.55
<b>GPPAQ</b>						
Inactive vs. moderately inactive	88	-0.45 (0.61)	Exp(B) 0.64	0.19 to 2.08	0.24 to 1.72	0.29 to 1.38
Inactive vs. moderately active		-0.51 (0.42)	Exp(B) 1.22	0.39 to 3.80	0.47 to 3.17	0.58 to 2.57
Inactive vs. active		-0.76 (0.46)	Exp(B) 1.86	0.58 to 5.95	0.70 to 4.94	0.87 to 3.98
Work performance (0–10) – higher score = less able to do job	95	0.02	0.13 (0.66)	-1.19 to 1.45	-0.97 to 1.23	-0.72 to 0.99
Work absenteeism (0–100) – higher score = more time off	80	0.11	10.31 (10.49)	-10.58 to 31.20	-7.16 to 27.78	-3.25 to 23.87
Work presenteeism (0–100) – higher score = more presenteeism	62	0.06	3.49 (7.22)	-10.96 to 17.94	-8.58 to 15.56	-5.87 to 12.85
Work productivity (0–100) – higher score = lower productivity	56	0.14	8.63 (8.59)	-8.60 to 25.85	-5.75 to 23.01	-2.52 to 19.77
Work impairment (0–100) – higher score = increased impairment	92	0.12	6.90 (5.90)	-4.81 to 18.61	-2.90 to 16.70	-0.71 to 14.51
Work satisfaction (0–10) – higher score = increased satisfaction	87	0.01	-0.04 (0.61)	-1.24 to 1.17	-1.04 to 0.97	-0.82 to 0.75
HRQoL (-0.59–1.00) – higher score = better health	91	0.28	-0.15 (5.45)	-0.26 to -0.04	-0.24 to -0.06	-0.22 to -0.08
Perceived change (1–6)	98	0.01	0.03	-0.42 to 0.47	-0.34 to 0.40	-0.26 to 0.31

DV, dependent variable; IV, independent variable.

## Appendix 7

**TABLE 11** Testing of mediation pathways prior to running mediation analysis: *b* path (potential mediator scores at 6-week follow-up as IV; time off work PLUS SMS DATA at 6-month follow-up as DV) – Group A only (1000 bootstrapped samples, unless otherwise indicated)

Potential mediator (measured at 6 weeks)	<i>n</i> in each model	<i>R</i> (standardised beta)	Adjusted <i>R</i> <sup>2</sup>	Unstandardised beta (SE)	Bootstrapped 95% CI
SF-12 PCS (0–100)	48	–0.47	0.20	–1.50 (0.46)	–2.28 to –0.46 <sup>a</sup>
SF-12 MCS (0–100)	48	0.06	–0.02	–0.21 (0.38)	–0.93 to 0.57
Depression [PHQ-8] (0–24)	49	0.15	0.00	1.03 (1.09)	–1.29 to 3.14
Anxiety [GAD-7] (0–21)	49	0.01	–0.02	–0.05 (1.02)	–2.15 to 1.90
Attitudes and Beliefs scale (0–60)	43	0.07	–0.02	0.40 (0.97)	–1.61 to 2.23
RTW SE (0–10)	48	–0.42	0.16	–7.66 (2.52)	–13.16 to –3.18 <sup>a</sup>
<b>GPPAQ</b>					
Inactive vs. moderately inactive	46	0.55	0.26	56.94 (22.05)	12.35 to 101.67
Inactive vs. moderately active				10.50 (16.05)	–16.46 to 45.00
Inactive vs. active				–10.28 (6.79)	–26.54 to 0.75
Work performance (0–10)	47	0.44	0.17	5.40 (1.62)	2.25 to 8.82 <sup>a</sup>
Work absenteeism (0–100)	41	0.61	0.36	0.51 (0.13)	0.25 to 0.78 <sup>a</sup>
Work presenteeism (0–100)	35	0.44	0.17	0.57 (0.24)	0.12 to 1.09 <sup>a,b</sup>
Work productivity (0–100)	31	0.51	0.23	0.52 (0.24)	0.04 to 1.00 <sup>b</sup>
Work impairment (0–100)	49	0.44	0.18	0.71 (0.21)	0.34 to 1.18 <sup>a</sup>
Work satisfaction (0–10)	44	0.11	–0.03	–1.41 (2.44)	–5.61 to 3.98
HRQoL (–0.59 to 1.00)	49	0.52	0.25	–0.98 (0.23)	–1.45 to –0.50 <sup>c</sup>
Perceived change (1–6)	50	0.57	0.31	19.59 (4.37)	10.87 to 20.09 <sup>a</sup>

EQ-5D, EuroQol-5 Dimensions.

<sup>a</sup>  $p < 0.05$ .

<sup>b</sup> < 1000 bootstrapped samples: presenteeism = 999; productivity = 988; GPPAQ = 995.

<sup>c</sup> EQ-5D scaled by 100 to aid interpretation.

## Appendix 8

**TABLE 12** Testing of mediation pathways prior to running mediation analysis: *b* path (potential mediator scores at 6-week follow-up as IV; time off work PLUS SMS DATA at 6-month follow-up as DV) – Group B only (1000 bootstrapped samples, unless otherwise indicated)

Potential mediator (measured at 6 weeks)	<i>n</i> in each model	<i>R</i> (standardised beta)	Adjusted <i>R</i> <sup>2</sup>	Unstandardised beta (SE)	Bootstrapped 95% CI
SF-12 PCS (0–100)	40	–0.53	0.26	–1.96 (0.55)	–2.94 to –0.71 <sup>a</sup>
SF-12 MCS (0–100)	40	–0.40	0.14	–1.51 (0.69)	–3.08 to –0.26 <sup>a</sup>
Depression [PHQ-8] (0–24)	42	0.39	0.14	3.16 (1.38)	0.06 to 5.68 <sup>a</sup>
Anxiety [GAD-7] (0–21)	41	0.39	0.13	3.12 (1.42)	0.49 to 6.02 <sup>a</sup>
Attitudes and Beliefs scale (0–60)	40	0.07	–0.02	0.52 (1.10)	–1.86 to 2.67
RTW SE (0–10)	41	–0.46	0.19	–9.35 (2.98)	–15.31 to –3.69 <sup>a</sup>
GPPAQ					
Inactive vs. moderately inactive	41	0.09	–0.07	–10.36 (20.86)	–51.84 to 32.13
Inactive vs. moderately active				–8.94 (20.97)	–50.21 to 35.32
Inactive vs. active				–5.97 (25.01)	–48.32 to 44.50
Work performance (0–10)	47	0.60	0.35	8.88 (1.85)	5.20 to 12.49 <sup>a</sup>
Work absenteeism (0–100)	38	0.70	0.48	0.74 (0.13)	0.49 to 1.10 <sup>a</sup>
Work presenteeism (0–100)	26	0.39	0.12	0.54 (0.34)	0.03 to 1.23 <sup>a</sup>
Work productivity (0–100)	24	0.49	0.21	0.61 (0.49)	0.14 to 1.09 <sup>a</sup>
Work impairment (0–100)	42	0.43	0.17	0.67 (0.22)	0.28 to 1.10 <sup>a</sup>
Work satisfaction (0–10)	42	0.05	–0.02	–0.83 (3.03)	–6.15 to 5.85
HRQoL <sup>b</sup> (–0.59 to 1.00)	41	–0.42	0.16	–0.70 (0.24)	–1.18 to –0.21 <sup>a</sup>
Perceived change (1–6)	47	0.69	0.46	31.69 (5.23)	20.24 to 30.85 <sup>a</sup>

<sup>a</sup>  $p < 0.05$ .

<sup>b</sup> EQ-5D scaled by 100 to aid interpretation.