

**The WORKWELL programme: a randomised controlled trial of job retention vocational rehabilitation for people with inflammatory arthritis**

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The WORKWELL programme: a randomised controlled trial of job retention vocational rehabilitation for people with inflammatory arthritis.

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**Objective:** People with inflammatory arthritis (IA) frequently experience work instability, absenteeism, and reduced productivity, culminating in early job loss. This study evaluated the effectiveness and cost-effectiveness of WORKWELL job retention vocational rehabilitation (JRVR) delivered by occupational therapists, compared to a control group receiving written self-help advice.

**Methods:** A pragmatic, multi-centre randomised controlled trial was conducted across 18 UK NHS Trusts. Employed adults (n=249) with IA experiencing moderate to severe work instability, were randomised (1:1) to intervention or control groups. WORKWELL included structured work assessment, individually tailored action plans, and interventions over 2-4 months. Follow-up was at 6, 12, and 36 months. The primary outcome was the Work Limitations Questionnaire-25 (WLQ-25). Analyses used linear mixed-effects regression adjusted for baseline characteristics and occupational skill level. An NHS perspective was used for the within-trial cost-effectiveness analysis. Much of the trial was affected by the COVID-19 pandemic.

**Results:** At 12 months, there was no significant difference in WLQ-25 between groups (adjusted mean difference: -1.8; 95% CI -7.4 to 3.8; p=0.53), or in most secondary outcomes at 12- or 36-months. However, absenteeism showed a relative reduction of 46% at 12 months (p=0.08), and employment retention at 36 months was higher in the intervention (93%) vs. control group (85%). The intervention was not cost-effective from an NHS perspective.

**Conclusion:** WORKWELL did not lead to improved work productivity compared to self-help advice. Future research should explore more flexible delivery methods, including digital tools,

90 to support sustainable employment for people with IA. A plain-language abstract is available  
91 in the supplementary material.

92 **Trial registration:** ClinicalTrials.gov; NCT03942783. ISRCTN Registry; ISRCTN61762297.

93

94 **Keywords:** Inflammatory arthritis; Vocational rehabilitation; Job retention; Occupational  
95 therapy; Randomised controlled trial; Work productivity; Presenteeism; Employment  
96 outcomes; Self-management; Rheumatology rehabilitation

97

98 **Key Messages:**

99 1. The WORKWELL wasn't effective or cost-effective in the NHS, though wider  
100 societal benefits remain unmeasured.

101 2. At 36 months, most participants in both groups remained in paid work, with no  
102 significant differences between the intervention and control arms.

103 3. Future approaches to supporting work participation in people with inflammatory  
104 arthritis should explore more flexible, scalable delivery models, including digital self-help tools.

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**Introduction**

Work ability decreases in employed people with inflammatory arthritis (IA). Amongst those with rheumatoid arthritis (RA), 40-67% experience presenteeism (reduced work productivity), 30-84% absenteeism, and 50% stop working within 4.5-22 years of diagnosis, despite modern medication [1-3]. Employment rates have changed little from 1980 to 2022 [4].

Job retention vocational rehabilitation (JRVR) is a work-focused intervention helping employed individuals with health conditions stay in work by addressing job-related challenges through tailored support, workplace strategies, and self-management. As work impacts occur early, JRVR can potentially keep people with IA working. The European Alliance of Associations for Rheumatology (EULAR) recommends using the biopsychosocial framework of health to address work needs, sustain work ability and productivity, and prevent long-term absence [5].

Two recent systematic reviews highlighted inconsistent results of JRVR in IA [6,7]. Two Dutch trials of multidisciplinary JRVR (n=150;1-2y follow-up) showed no evidence of effect on work outcomes [8-10]. In one, initially 40% of participants were on long-term sick leave, meaning JRVR was potentially too late [8]. In the other, initially 50% had little presenteeism and work instability (a mismatch between ability and job demands), suggesting JRVR was too early [10].

Two small UK trials (n ≤55) with short follow-up (6-9m), recruiting participants with moderate to severe work instability indicated beneficial effects on presenteeism [11,12]. Two longer US trials (2-4.5y follow-up) reduced job loss [13,14], although not presenteeism [15]. Interventions in the latter four trials tested JRVR delivered by a single professional (either a VR counsellor, occupational therapist or physiotherapist). The findings suggest that tailored JRVR, delivered by a consistent professional with VR training, have some beneficial effects on work outcomes.

Cost-effectiveness evidence is required for resource allocation decision-making [15].



Work participation is a complex interplay between biopsychosocial consequences of health-related, personal and environmental contextual factors [16]. These factors help explain the impact of arthritis on work participation and can modify the effects of work-focussed interventions [17-19]. Factors influencing remaining in work and fewer work limitations include younger age (<50 years), higher education, shorter disease duration, no comorbidities, lower disease activity, less pain, less fatigue and better function, better psychological status, less physically and mentally demanding jobs, higher work self-efficacy, and workplace support [4, 20, 21]. EULAR guidance recommends including such factors in trials of work outcomes in IA to examine their effects [22]. These findings highlight that work participation is determined by interacting clinical, personal and occupational factors, rather than disease status alone. Interventions aiming to improve work outcomes therefore need to address this broader context, including workplace demands, individual capacity, and self-management. Vocational rehabilitation interventions are designed to target these multiple determinants by supporting individuals to adapt work tasks, manage symptoms, and negotiate workplace adjustments.

The aims of this study were to: (i) examine the effects of WORKWELL JRVR on presenteeism and other work outcomes at 6-, 12- and 36-months post-randomisation among people with IA experiencing work instability; (ii) investigate what contextual factors (if any) influenced the results; and (iii) assess the cost-effectiveness of WORKWELL for resource allocation decision-making.

## Method

Study design and ethics.

The WORKWELL trial was a definitive, pragmatic, multi-centre superiority randomised controlled trial (RCT). Ethical approval was obtained on 15/11/2018 (West Midlands – Solihull Research Ethics Committee:18/WM/0327). Participants were recruited from 18 National

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3 159 Health Service (NHS) Trust rheumatology departments in England, Wales, and Scotland.  
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5 160 Sites opened from February to August 2019, following each site's approval. Initially, a 12m  
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7 161 follow-up was approved, with 36m follow-up approved later. The first participant was  
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9 162 randomised in March 2019, and the last in February 2021. The last 12m questionnaire was  
10  
11 163 returned in March 2022, and last 36m questionnaire in March 2024. Trial and process  
12  
13 164 evaluation protocols have been published [23, 24]. The CONSolidated Standards of Reporting  
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15 165 Trials (CONSORT) reporting guidelines were followed [25, 26].  
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21 167 Participants  
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23  
24 168 Inclusion criteria were: aged  $\geq 18$  years, diagnosed with RA, early IA (EIA, i.e., not meeting full  
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26 169 diagnostic criteria for RA but treated as if RA) or psoriatic arthritis (PsA) by a rheumatology  
27  
28 170 consultant; in paid work for  $\geq 15$  hours/ week; and experiencing work instability (score  $\geq 10$   
29  
30 171 on the RA-Work Instability Scale (RA-WIS), i.e., at medium to high risk of work instability  
31  
32 172 meaning JRVr is appropriate) [27]. Exclusion criteria were on long-term sick leave ( $> 4$  four  
33  
34 173 weeks); retiring in  $\leq 12$ m; and already receiving JRVr. Rheumatology clinicians or therapists  
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36 174 identified patients during appointments, from department databases, or medical or therapy  
37  
38 175 records. Patients were provided with an invitation letter and information sheet. If interested,  
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40 176 they were screened (in person or by telephone) by an NHS research practitioner, therapist, or  
41  
42 177 member of the research team, and the study explained. Eligible patients provided written  
43  
44 178 consent. The baseline questionnaire was completed at home and mailed to the trial manager.  
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46 179 Freepost envelopes were provided throughout the trial for postal returns.  
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50 180 Recruitment primarily occurred through NHS rheumatology services. During the COVID-19  
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52 181 pandemic, when recruitment slowed due to reduced clinical capacity and fewer eligible  
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54 182 patients in employment, additional participants were recruited through two national arthritis  
55  
56 183 charities. These organisations disseminated study information to individuals with IA who were  
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58 184 invited to contact the research team directly for eligibility screening.  
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185 Interventions

186 Both groups continued receiving usual care.

187

188 *Control group*

189 Participants received a work self-help information pack about coping at work, sources of help  
190 and employment rights, with a letter encouraging them to read the booklets enclosed, identify  
191 work problems and find solutions [24].

192

193 *Intervention group*

194 Participants received the same information pack. WORKWELL sessions were held in person,  
195 with flexible appointment times, usually at the applicable Therapy department. JRVR included  
196 a structured work assessment (the Work Experience Survey–Rheumatic Conditions (UK  
197 WES-RC) [28], prioritised goals, and tailored support including self-management, job  
198 accommodations, and employer communication. Up to four sessions were delivered over 2–  
199 4 months, followed by a brief telephone review. A work site visit and/or letters for employers  
200 about work support recommended were offered, if required [23, 24].

201

202 Therapist training

203 Occupational therapists, with experience supporting employed people with IA, delivered  
204 WORKWELL. Beforehand, therapists completed a JRVR training programme, demonstrated  
205 competency in a mock WES-RC and JRVR plan. Ongoing support was available via  
206 mentoring, peer discussion by email, and the WORKWELL Solutions Manual (including  
207 biopsychosocial strategies for addressing work-related problems) [29].

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209 Randomisation, procedures and blinding

210 Following baseline questionnaire receipt, participants were assigned 1:1 to intervention or

211 control groups, and stratified by job skill level (i.e., low: categories 1 to 2; or high: categories 3

212 to 4) using the Office for National Statistics classification [30]. Job skill level was selected as

213 a stratification factor because occupational demands and job control are known to influence

214 work functioning and the ability to remain in employment among people with IA. Stratification

215 was by permuted blocks of random sizes (4, 6 or 8) conducted by the Lancashire Clinical Trials

216 Unit (LCTU) using Sealed Envelope, a web-based central randomisation service [31].

217 Participants were allocated to both groups from the start of recruitment at each site. After

218 randomisation, the LCTU mailed all participants the information pack and referred

219 WORKWELL participants to the relevant therapist. Therapists contacted participants within

220 five days of referral and JRVR began within four weeks. Participating therapists were

221 unblinded to group allocation. Data management staff were blinded to group allocation, as

222 was the trial statistician when conducting the primary outcome analysis at 12m [23].

223

224 Data collection

225 The postal baseline questionnaire collected demographic (e.g., age, sex, education),

226 employment (e.g., job title, hours worked, organisation size) and health and healthcare

227 resource use information. This included detailed information on prescribed medications

228 (csDMARDs, biologic and targeted therapies, and corticosteroids). All outcomes were

229 collected using validated self-reported questionnaires widely used in occupational health and

230 rheumatology research. These instruments are designed for self-completion and capture

231 perceived work limitations, work instability and productivity. Data quality was supported

232 through structured follow-up procedures, including reminders and telephone completion of

233 minimum datasets where questionnaires were not returned.

234 Outcomes were collected using questionnaires at 6m, 12m, and 36m. Follow-up  
235 questionnaires were available as mailed paper copies or online, with an e-mailed secure  
236 weblink. If not returned, after two weeks, participants were sent a text/ email/ telephone  
237 reminder, and at three weeks a second questionnaire copy or weblink. At four weeks, if not  
238 returned, trial managers attempted to collect a minimum dataset by telephone [23].  
239 Intervention participants not completing JRVr continued in follow-up unless they withdrew.

240

## 241 Outcomes

242 The primary outcome, at 12m post-randomisation, was the Work Limitations Questionnaire-  
243 25 (WLQ-25PDmod), a measure of presenteeism [32], as modified in 2016 [33], using the  
244 summed score of the four sub-scales. Secondary outcomes included these WLQ sub-scales,  
245 WLQ-25PDMod productivity loss score, and the Workplace Activities Limitations Scale  
246 (WALS-12, 12 items, measuring work ability) [21]. The WLQ-25PDmod and WALS-12 were  
247 collected using the dual-key scored outcome measure. Both were scored using the original  
248 and dual-key methods, as the latter is more sensitive to change [34].

249 The scales used in this study have established scoring ranges and directions of interpretation.  
250 For the WLQ-25PDmod, higher scores indicate greater work limitations and reduced  
251 productivity. The WALS-12 ranges from 0–36, with higher scores reflecting greater difficulty  
252 performing work activities. The RA-Work Instability Scale (RA-WIS) ranges from 0–23, with  
253 higher scores indicating greater risk of work instability. The Work Self-Efficacy scale measures  
254 confidence in managing work demands, with higher scores indicating greater self-efficacy.  
255 The RA Impact of Disease (RAID) and RA-Disease Activity Index-5 (RADAI-5) both range  
256 from 0–10, with higher scores indicating greater disease impact or activity. For all measures,  
257 negative change scores represent improvement where higher scores denote worse outcomes.

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3 259 Other secondary outcomes were the Work Productivity and Activity Impairment questionnaire  
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5 260 v2.0 (WPAI) (0m, 6m, 12m) [35]; employment status; absenteeism (number of days off sick,  
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7 261 collected monthly by text, email or telephone) (0 through 12m); the RA-Work Instability Scale  
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9 262 (RA-WIS) (0m, 12m) [27]; Work Self-Efficacy (WSE) (0m, 12m); and satisfaction with work  
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11 263 support received (6m).  
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17 265 Analysis of contextual factors, potentially influencing the intervention’s impact on the primary  
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19 266 outcome, included (0m, 12m): the Short-Form12v2 Health Survey (SF12v2) [36], RA Impact  
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21 267 of Disease (RAID) [37] and RA-Disease Activity Index-5 (RADAI-5) [38]; job skill level (0m,  
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23 268 12m, 36m) [30]; Work Demands (WD) (0m,12m) [39]; and Rheumatic Disease Comorbidities  
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25 269 Index (0m) [40]. Although RA-specific instruments were originally developed for RA  
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27 270 populations, they capture domains such as pain, fatigue, function and disease impact that are  
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29 271 common across IA conditions, including early IA and PsA. These instruments have therefore  
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31 272 been used in mixed IA cohorts to provide consistent patient-reported outcome measurement.  
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34 273 For a within trial cost-effectiveness analysis (CEA), the EQ-5D-5L questionnaire was used  
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36 274 (0m, 6m,12m) to determine participants’ health-related related quality-of-life (HRQoL) [41], as  
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38 275 was NHS resource use via a participant questionnaire. This included use of hospital services  
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40 276 (e.g. inpatient / outpatient / day case / A&E), use of primary / community-based services (e.g.  
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42 277 General Practice / mental health services / occupational therapy), and any prescribed  
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44 278 medication. Resource use associated with delivering the intervention was determined from  
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46 279 trial documentation completed by therapists.  
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53 281 COVID-19 effects on trial and impacts.  
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55 282 The trial paused in March 2020 for safety reasons, with JRVR suspended. To enable re-start,  
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57 283 trial adaptations were discussed with the Patient and Public Involvement Group (PPIG) and  
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59 284 therapists. Following site approval, 13 sites re-started in July or August 2020, and five between  
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September 2020 and January 2021. Periodic lockdowns (restrictions on the public's movements) continued until April 2021. Non-essential workers worked remotely from home (WRFH) until January 2022. If unable to WRFH, they could be furloughed (the Coronavirus Job Retention Scheme) until September 2021. Essential workers continued attending work throughout. Participants in follow-up received questionnaires to schedule. At 6m and 12m, most participants completed questionnaires whilst COVID-19 restrictions were in place (6m: n=174 (80%); 12m n = 192 (94%)).

Following re-start, recruitment slowed due to reduced site staff availability and fewer eligible patients due to job loss or furlough. Additional participants were recruited via two arthritis charities to reach the target sample size.

At restart, the trial website included downloadable documents for electronic completion, and an online Workwell Solutions Manual. JRVR was delivered remotely by telephone or videoconferencing. In-person treatment became possible later. Two therapists in the research team provided participants' JRVR remotely for seven sites, due to therapist redeployment or sickness, and treated charity-recruited participants. Normally, participants were treated by one therapist, occasionally by a second if the original unavailable [42].

#### Sample size

To identify a minimal clinically important difference (13 points) [43] in the primary outcome at 12m, assuming 90% power, SD=23.02 (conservative estimate from our feasibility trial [12, 23]), 5% significance level, and an intra-class correlation coefficient (ICC) of 0.05 in the intervention arm to account for a potential therapist clustering effect (with an average of 5 (variance=5) participants per therapist), 90 participants were needed in each group [24]. Allowing for a 25% drop-out, the recruitment target was 240.

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Statistical analysis

The analysis followed a pre-specified Statistical Analysis Plan<sup>1</sup> and was by intention-to-treat, using STATA version 17 [44]. Baseline characteristics were described overall and by group, reporting mean (SD), median (IQR) or number (proportion) as appropriate. Primary effectiveness analysis used a linear mixed-effects (lme) regression model to estimate the effect of group allocation on WLQ-25PDmod scores at 6m, 12m and 36m, controlling for the stratification variable (job skill level) and baseline value of the WLQ-25PDmod. A participant-specific random effect nested within a therapist-level random effect was specified. As the therapist effect only occurred in those who received the WORKWELL intervention, this was a partially-nested design. Therapist effect was allocated by the therapist seen most frequently. The model estimated the variance of residual errors separately in the intervention groups to allow for between-group heteroscedasticity. Outcomes were analysed in a single model with an interaction term between time-point and intervention group to determine the treatment effect at each time-point separately. Of primary interest was the treatment effect at 12 months. Sensitivity analyses using alternative definitions of a per-protocol analyses were conducted: 1) excluding intervention participants not receiving JRVR, and control participants reporting at 12m they received JRVR; and 2) excluding intervention participants not receiving JRVR or only attending the first treatment appointment (i.e., work assessment), and control participants reporting receiving JRVR. Secondary outcome analyses also used appropriate generalised linear mixed effects modelling methods (i.e., linear, logistic, or ordinal logistic), controlling for the stratification variable, baseline value of that outcome variable, and random therapist effect. The interaction between time-point and group was not included for measures collected post-randomisation at 12m only.

<sup>1</sup> There was a minor deviation from the SAP. We originally analysed the 6/12 months results in a 2-time point longitudinal model, in a blinded analysis, as described in the SAP, and we planned to analyse the 36-month outcomes in a separate 1--timepoint model. However, we later decided to publish all time points together in this article, and to avoid confusion, we analysed the 6-,12- and 36-month outcomes in one 3-time point model, which could not be blinded. The findings were not sensitive to the model fitted, so this has not led to any changes in the results at any time point.



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336 We considered the association of various contextual factors with the primary outcome in an  
 337 exploratory analysis, adding a three-way interaction term (time-point, intervention group,  
 338 contextual factor) into the main model.

339

340 The primary within-trial economic evaluation followed the NICE reference case [45]. Published  
 341 unit costs were attached to reported NHS resource use. Quality-adjusted life-years (QALYS)  
 342 were calculated using utility scores mapped to reported EQ-5D-5L states [46]. Missing cost  
 343 and outcomes data were imputed using multiple imputation by chained equations in STATA.  
 344 Costs and QALYs were adjusted for previous NHS resource use prior to trial enrolment and  
 345 baseline HRQoL, respectively. An incremental cost-effectiveness ratio (ICER) was calculated  
 346 using the following:

347

$$\text{ICER} = \frac{(\text{Cost of JRVR} - \text{Cost of Control})}{(\text{Effectiveness of JRVR} - \text{Effectiveness of Control})}$$

349

350 The ICER represents the cost of generating an additional QALY using JRVR. An ICER under  
 351 the willingness-to-pay threshold of £20-30,000 is deemed cost-effective under current decision  
 352 rules [45]. Using the lower £20,000 bound of threshold, an incremental net monetary benefit  
 353 (INMB) was determined using the following:

354

$$\text{INMB} = \frac{\text{£20k} \times \text{Difference in Effectiveness between JRVR and Control}}{\text{Difference in Cost}}$$

356

357 A positive INMB indicates that JRVR is cost-effective from an NHS and Social Care  
 358 perspective. To generate confidence intervals around the ICER and INMB point estimates,  
 359 bootstrapping was used to recalculate costs and outcomes in 1000 resamples [47].

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**Results**

Recruitment and response rates

Figure 1 shows participant flow through the trial: 249 were randomised (control = 125; intervention = 124). Of these, 34 (14%) were recruited via charities. All participants were mailed the self-help information pack. Questionnaire response rates were: 216 (87%) at 6m; 204 (82%) at 12m; and 180 (72%) at 36m.

Participants

Participant mean age was 49 years, 81% were women, median time since diagnosis was 4.4 years, and 58% worked full-time. Demographic and employment characteristics are in table 1. At baseline, the mean WLQ-25PDmod summed score (0-100) was 30.9 (SD 17.0) in the control, and 30.8 (SD 19.8) in the intervention groups, i.e., low to moderate presenteeism (table 2). Baseline disease characteristics are presented in Supplementary Table S3. Participants had moderate disease impact at study entry, with mean RAID scores of approximately 6 and RADAI-5 scores between 5 and 6, indicating ongoing disease burden despite treatment. Approximately one third of participants had early disease ( $\leq 2$  years duration). Participants had a mean duration of current employment of 11.0 years (SD 9.8), suggesting relatively stable employment at study entry. The majority of participants were employed on permanent contracts (95.2%), indicating a relatively stable employed population at study entry.

Intervention provision

Overall, 96/124 (77%) completed JRVr, of whom: 30/33 were treated before the pandemic, 24/36 were paused participants, and 42/55 recruited after re-start (supplementary table S1). Of 355 appointments, 189 (53%) were in-person, 106 (30%) telephone, 60 (17%) videocall.

26 (21%) participants were treated by research team therapists. On average, participants received 3.6 (SD1.5) appointments. Work barriers identified are detailed elsewhere [31]. Intervention delivery was not contingent on continued employment, and participants were able to continue receiving the intervention where appropriate. During the trial, a small proportion of participants reported changes in employment status; however, most remained in work at 12 months (97.2% control; 98.0% intervention).

393

#### 394 Primary outcome

The regression model was analysed longitudinally based on 219/249 (88%; 114 control and 105 intervention) of randomised participants with a baseline and at least one 6m, 12m or 36m follow-up score. At 12m, the primary endpoint, after adjusting for the stratification variable and baseline scores there was no evidence of an effect of the intervention on presenteeism, compared to the control group (adjusted mean difference of -1.8 (95% CI: -7.4 to 3.8),  $p=0.53$ ). Whilst the point estimate of -1.8 favoured the intervention, the lower confidence limit (-7.4) did not extend beyond the clinically important difference of -13. At 36m the trial also found no evidence of an effect (-3.0 (95% CI -9.4 to 3.5,  $p = 0.37$ ). Results are shown in table 2 and sensitivity analyses in supplementary table S2.

404

#### 405 Secondary outcomes

Across the secondary outcomes, at all three time-points, mean differences between the two groups were mostly small and, while favouring the intervention group, were not statistically significant. Those approaching statistical significance were the WLQ-25 mental-interpersonal demands scale (6m) ( $p=0.07$ ), absenteeism, with a relative reduction of 46% (12m) (95% CI: 73% reduction to a 7% relative increase,  $p=0.08$ ), and the WALIS-12 (36m) ( $p=0.07$ ) (table 2). Health outcomes remained stable from 0-12m (table 3). At 12m, satisfaction with work advice received was higher in the intervention (8.7/10, SD 1.6) than control group (7.2/10, SD 2.5). At 12m, most participants remained employed, although by 36m employment was higher in

the intervention group (93%) compared to control (85%). The proportion changing jobs due to health was higher at 36m in the intervention group (15%) compared to control (7%).

#### Contextual factors analysis

Most personal, environmental and health-related variables explored were not found to be contextual factors influencing the level of the primary outcome. There was a trend towards a significant interaction for Work Demands help from colleagues at 36m ( $p=0.08$ ), and a significant interaction for Work Demands mentally demanding work ( $p=0.02$ ). However, the group with little/no mentally demanding work was small at baseline ( $n=17$ ) (table 4, supplementary tables S3 and S4).

423

#### Cost-effectiveness analysis

There was little observed between-group difference in either costs or outcomes (table 5). The mean INMB from 1000 bootstrapped resamples was -£196 (pseudo 95% CI: -£1,712 to £1,239). Over 40% of bootstrapped ICERs indicated that JRVR was more expensive and less effective (Supplementary Figure S1). The probability that the intervention would be considered cost-effective under current decision rules was 6.38% (Supplementary Figure S2).

430

#### Adverse events

No adverse events resulting from trial participation were reported.

433

### Discussion

This study found no evidence of a clinically important effect of the WORKWELL JRVR intervention on work participation outcomes at 6, 12 or 36 months. Differences between groups were small across all timepoints and outcomes, and consistent across sensitivity analyses. From an NHS and Social Care perspective, WORKWELL is unlikely to be cost-effective within this study given the higher associated costs without improvement in HRQoL. The findings suggest that, within this cohort of individuals with IA who had relatively short disease duration and were largely established in employment, the WORKWELL JRVR

intervention did not provide additional benefit beyond usual care. The high proportion of participants remaining in work throughout the study and relatively stable employment characteristics at baseline may have limited the scope for improvement.

In this study, no meaningful differences were observed between groups across work outcomes, despite a structured and tailored intervention. The high employment retention and relatively stable baseline employment characteristics suggest limited scope for improvement in this population. Previous trials of JRVR have reported mixed findings, with some showing benefits in specific contexts. Participant interviews in the present study suggested that factors such as the timing of intervention, workplace support, and flexibility of delivery may influence effectiveness. Participants with longer disease duration may already have adapted their work roles, reducing the potential additional impact of the intervention [48].

To further understand these findings, process evaluation data provide additional context. The intervention was well received by therapists and participants and showed good fidelity during delivery [48,49]. Therapist interviews suggested that, although positive about remote delivery, additional workload pressures arising from the pandemic may have reduced its impact [49]. These insights highlight the importance of adaptable, co-designed, tailored solutions, for which further research is needed.

The high employment retention rate at 36m in both groups (over 80%) indicates that most participants remained in work throughout the study, which may have limited the potential for additional benefit from the WORKWELL JRVR intervention. Both groups also received written self-help advice, which may have contributed to maintaining work participation. Process evaluation findings indicated that the self-help pack helped participants in understanding their employment rights and prompted some to seek additional work support [48].

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3 469 Our study was large, pragmatic, focused on people with medium to high risk of work instability,  
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5 470 and included an economic evaluation. However, the COVID-19 pandemic had a major impact  
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7 471 throughout the trial. Many participants were WRFH, with potential benefits from reduced  
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9 472 commuting, increased work flexibility, and ability to self-manage their condition but also  
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11 473 disadvantages of increased stress and poorer work facilities. Others were furloughed and  
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13 474 essential workers found their jobs increasingly pressured [50]. JRVR delivery was affected  
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15 475 and JRVR completion rates reduced, potentially masking JRVR benefits.  
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20 477 There were some limitations. The WLQ-25PDmod, WALs and WPAI ask about recent (1–2  
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22 478 weeks) work difficulties. If participants were not working, furloughed or on long-term sick leave  
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24 479 at follow-ups, these could not be completed, limiting capturing presenteeism changes. Many  
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26 480 participants were white, on permanent contracts in large organisations, and the sample thus  
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28 481 does not fully reflect the working population. A number of assumptions had to be made for  
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30 482 costing NHS resource use due to an absence of data. This could have had an impact on the  
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32 483 cost estimates for both interventions. There may also be wider societal impacts and  
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34 484 effectiveness which we could not measure in this RCT.  
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39 486 This trial demonstrates the feasibility of delivering tailored JRVR within routine rheumatology  
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41 487 services, even during a pandemic. The findings, in the light of the participant interviews, raise  
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43 488 questions about the optimal design and timing of JRVR, which may be more effective earlier  
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45 489 in the disease course, or at key employment transition points. Furthermore, scalable  
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47 490 approaches combining interactive digital tools, short interventions, and tailored self-guided  
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49 491 resources could help meet diverse needs across clinical and occupational settings.  
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54 493 In conclusion, although WORKWELL JRVR did not significantly improve work outcomes, it  
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56 494 represents an important step in testing pragmatic JRVR within NHS services. Future research  
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58 495 should focus on personalisation, digital delivery, and integration with employer-facing support  
59  
60 496 to enhance sustainability and effectiveness.

497

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529 **Ethics**

530 Ethical approval was received from the Health Research Authority West Midlands - Solihull  
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534 **Data availability Statement**

535 The data underlying this article will be shared on reasonable request to the corresponding  
536 author.

538 **Trial registration**

539 ClinicalTrials.gov NCT03942783. Registered on 08 May 2019. ISRCTN Registry  
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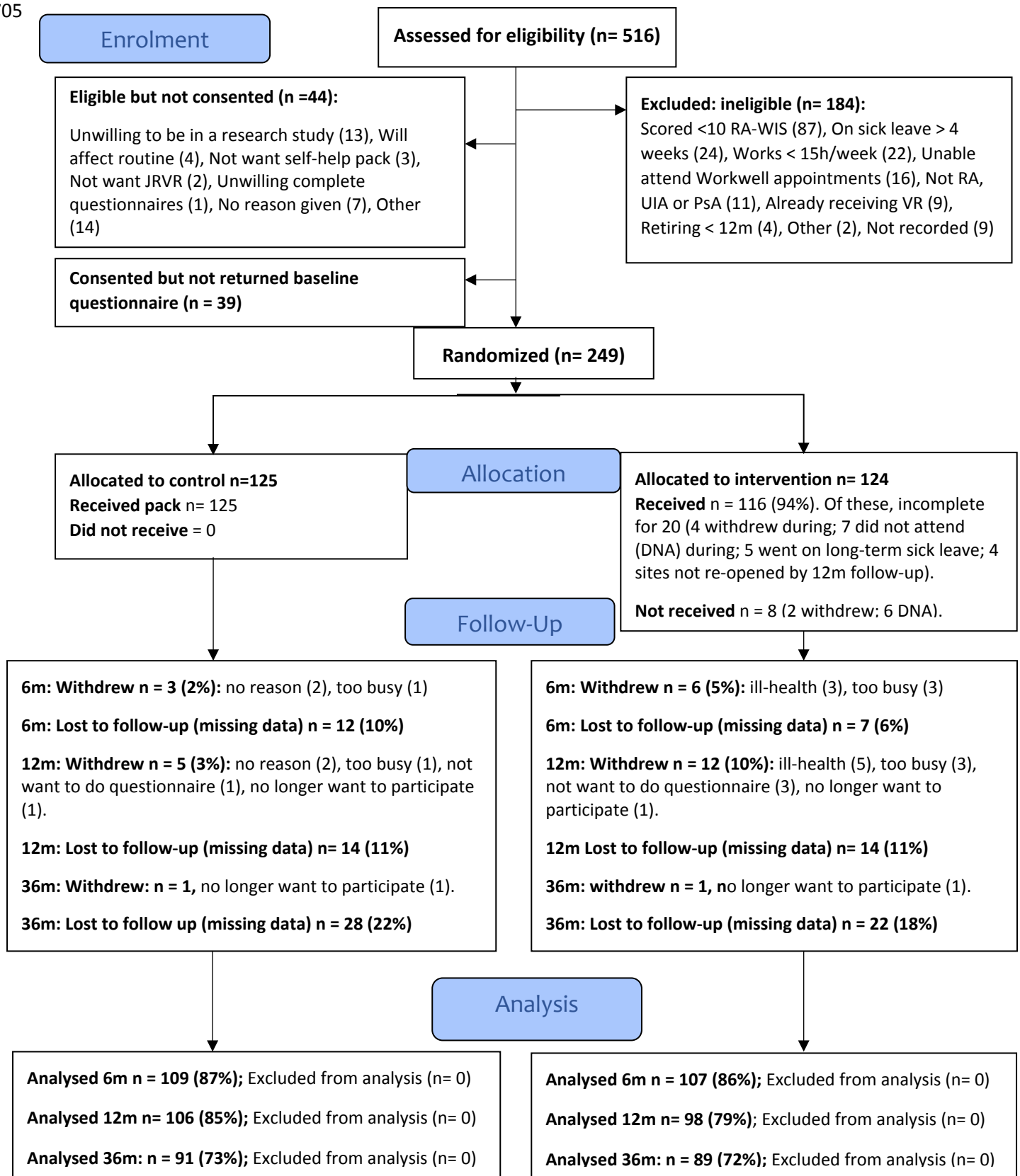
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**Figure 1: Workwell CONSORT Flow Diagram**

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706 **Alt Text:** A CONSORT flow diagram for the WORKWELL trial showing participant progression from assessment to analysis. Of 516 people  
707 assessed, 249 were randomised: 125 to control and 124 to the intervention. The diagram details reasons for ineligibility, non-consent, and  
708 missing baseline questionnaires. It shows numbers receiving the intervention or control materials, withdrawals, losses to follow-up at 6, 12, and  
709 36 months, and final numbers analysed: control (109 at 6m, 106 at 12m, 91 at 36m) and intervention (107 at 6m, 98 at 12m, 89 at 36m).

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711 **Table 1: Baseline participant demographic and employment characteristics (n = 249)**

|                                            | Control (n = 125)            | Intervention (n =124)       | Overall (n = 249)            |
|--------------------------------------------|------------------------------|-----------------------------|------------------------------|
| <b>Demographic:</b>                        |                              |                             |                              |
| Age (years), mean (SD)                     | 48.3 (10.2)                  | 48.8 (9.5)                  | 48.6 (9.9)                   |
| Sex (female/male/prefer not to say), n (%) | 105 (84.0)/19 (15.2)/1 (0.8) | 97 (78.2)/26 (21.0)/1 (0.8) | 202 (81.1)/45 (18.1)/2 (0.8) |
| Diagnosis, n (%)                           |                              |                             |                              |
| - RA                                       | 81 (64.8)                    | 84 (67.7)                   | 165 (66.3)                   |
| - Early IA                                 | 10 (8.0)                     | 13 (10.5)                   | 23 (9.2)                     |
| - PsA                                      | 24 (27.2)                    | 27 (21.8)                   | 61 (24.5)                    |
| Time since diagnosis (years), median (IQR) | 4.0 (1.4, 10.5)              | 5.0 (1.2, 11.3)             | 4.4 (1.3, 10.6)              |
| Symptom duration (years), median (IQR)     | 6.0 (2.8, 13.0)              | 6.5 (2.8, 13.3)             | 6.0 (2.8, 13.3)              |
| Medication regimen, n (%)                  |                              |                             |                              |
| - 0 DMARD/ biologic/biosimilar             | 13 (10.4)                    | 6 (4.8)                     | 19 (7.6)                     |
| - 1 DMARD                                  | 37 (29.6)                    | 45 (36.3)                   | 82 (32.9)                    |
| - 2 or more DMARD                          | 30 (24.0)                    | 27 (21.8)                   | 57 (22.9)                    |



|                                                    | Control (n = 125) | Intervention (n =124) | Overall (n = 249) |
|----------------------------------------------------|-------------------|-----------------------|-------------------|
| - Biologics/ biosimilars (+/- DMARD)               | 45 (36.0)         | 46 (37.1)             | 91 (36.6)         |
| Living status, n (%)                               |                   |                       |                   |
| - Living alone                                     | 22 (17.6)         | 21 (16.9)             | 43 (17.3)         |
| - Living with family/ spouse/ significant other(s) | 103 (82.4)        | 103 (83.1)            | 206 (82.7)        |
| Education level, n (%)                             |                   |                       |                   |
| - Low education (ISCED 0 – 2)                      | 34 (27.2)         | 24 (19.4)             | 58 (23.3)         |
| - Medium education (ISCED 3 – 4)                   | 28 (22.4)         | 23 (18.6)             | 51 (20.5)         |
| - High education (ISCED 5 – 8)                     | 62 (49.6)         | 76 (61.3)             | 138 (55.4)        |
| - Missing                                          | 1 (0.8)           | 1 (0.8)               | 2 (0.8)           |
| Ethnic group, n (%)                                |                   |                       |                   |
| - White                                            | 122 (97.6)        | 120 (96.8)            | 242 (97.2)        |
| - Mixed/ multiple ethnic                           | 1 (0.8)           | 1 (0.8)               | 2 (0.8)           |
| - Asian/ Asian British                             | 1 (0.8)           | 1 (0.8)               | 2 (0.8)           |
| - Black/ African/ Caribbean/ Black British         | 0 (0.0)           | 0 (0.0)               | 0 (0.0)           |
| - Other                                            | 1 (0.8)           | 1 (0.8)               | 2 (0.8)           |
| - Prefer not to say                                | 0 (0.0)           | 1 (0.8)               | 1 (0.4)           |
| <b>Employment:</b>                                 |                   |                       |                   |
| Employment status, n (%)                           |                   |                       |                   |

|                                               | Control (n = 125) | Intervention (n =124) | Overall (n = 249) |
|-----------------------------------------------|-------------------|-----------------------|-------------------|
| - Full-time (≥ 35h/ week)                     | 69 (55.2)         | 75 (60.5)             | 144 (57.8)        |
| - Part-time (< 35h/week)                      | 56 (44.8)         | 49 (39.5)             | 105 (42.2)        |
| No. hours contracted to work/ week, mean (SD) | 30.9 (8.6)        | 33.2 (8.3)            | 32.1 (8.5)        |
| No. hours normally work/week, mean (SD)       | 33.2 (9.0)        | 35.2 (10.1)           | 34.2 (10.1)       |
| Job contract/ type, n (%)                     |                   |                       |                   |
| - Permanent contract                          | 108 (86.4)        | 111 (89.5)            | 219 (88.0)        |
| - Fixed term contract                         | 4 (3.2)           | 3 (2.4)               | 7 (2.8)           |
| - Zero hours contract                         | 1 (0.8)           | 0 (0.0)               | 1 (0.4)           |
| - Agency contract                             | 1 (0.8)           | 2 (1.6)               | 3 (1.2)           |
| Self-employed                                 | 11 (8.8)          | 8 (6.5)               | 19 (7.6)          |
| ONS Job Skill level, n (%)                    |                   |                       |                   |
| - 1 (lowest)                                  | 9 (7.2)           | 7 (5.6)               | 16 (6.4)          |
| - 2                                           | 49 (39.2)         | 51 (41.1)             | 100 (40.2)        |
| - 3                                           | 24 (19.2)         | 32 (25.8)             | 56 (22.5)         |
| - 4 (highest)                                 | 43 (34.4)         | 34 (27.4)             | 77 (30.9)         |
| Sole income earner (yes), n (%)               | 40 (32.0)         | 46 (37.1)             | 86 (34.5)         |
| Organization size (people), n (%)             |                   |                       |                   |
| - 1 person (self)                             | 9 (7.2)           | 6 (4.8)               | 15 (6.0)          |

|                                                                    | Control (n = 125)    | Intervention (n =124) | Overall (n = 249)    |
|--------------------------------------------------------------------|----------------------|-----------------------|----------------------|
| - Micro (2-9)                                                      | 9 (7.2)              | 6 (4.8)               | 15 (6.0)             |
| - Small (10-49)                                                    | 12 (9.6)             | 16 (12.9)             | 28 (11.2)            |
| - Medium (50-249)                                                  | 21 (16.8)            | 17 (13.7)             | 38 (15.3)            |
| - Large ( $\geq 250$ )                                             | 74 (59.2)            | 79 (63.7)             | 153 (61.5)           |
| Belong to a Trade Union/ professional organisation<br>(yes), n (%) | 52 (41.6)            | 51 (41.1)             | 103 (41.4)           |
| Disclosed condition to employer (yes/no), n (%)                    | 114 (91.2) / 2 (1.6) | 113 (91.1) / 4 (3.2)  | 227 (91.1) / 6 (2.4) |
| - Not applicable n, (%)                                            | 9 (7.2)              | 7 (5.6)               | 16 (6.4)             |
| Occupational Health available in main job (yes), n (%)             | 68 (57.1)            | 71 (58.7)             | 139 (57.9)           |

**Key:** DMARD = disease modifying anti-rheumatic drug; IA = inflammatory arthritis; ISCED = International Standard Classification of Education (ISCED 0 – 2 = no formal qualifications through to lower secondary education, e.g., GCSE; 3 – 4 = upper secondary, and post-secondary non-tertiary education, e.g., A Levels, BTEC, City & Guilds; 5 – 8 = short cycle tertiary (e.g., diploma), Bachelor/ Master/ PhD degrees); ONS = Office for National Statistics, Skill level: 1 = elementary occupations, 2 = administrative, caring, leisure, sales, customer service, process, plant, and machine operatives, 3 = skilled trades, associated technical and professional, 4 = professional, and managerial; PsA = psoriatic arthritis; RA = rheumatoid arthritis. + Medication regimen reflects the number of DMARD and/or biologic/biosimilar agents. Detailed medication classes (including csDMARDs, targeted therapies, biologics and corticosteroids) were collected at baseline but are not presented here.

721 **Table 2: Work outcome measures**

| Outcome, mean (SD) unless otherwise stated: | Time | n   | Control     | n   | Intervention | Adjusted difference in means (95% CI) | p    |
|---------------------------------------------|------|-----|-------------|-----|--------------|---------------------------------------|------|
| WLQ-25PDmod Summed score (0-100)            | 0m   | 125 | 30.9 (17.0) | 124 | 30.8 (19.8)  |                                       |      |
|                                             | 6m   | 101 | 32.2 (21.9) | 88  | 27.9 (18.1)  | -4.6 (-10.2, 1.1)                     | 0.11 |
|                                             | 12m  | 98  | 32.4 (22.6) | 91  | 30.4 (21.5)  | -1.8 (-7.4, 3.8)                      | 0.53 |
|                                             | 36m  | 70  | 35.2 (24.6) | 70  | 31.6 (21.8)  | -3.0 (-9.4, 3.5)                      | 0.37 |
| WLQ-25 Productivity Loss (%)                | 0m   | 121 | 8.2 (4.4)   | 122 | 8.0 (5.1)    |                                       |      |
|                                             | 6m   | 96  | 8.7 (5.8)   | 86  | 7.3 (4.9)    | -1.3 (-2.8, 0.3)                      | 0.11 |
|                                             | 12m  | 95  | 8.5 (5.9)   | 89  | 8.1 (5.7)    | -0.6 (-2.1, 0.9)                      | 0.45 |
|                                             | 36m  | 67  | 9.3 (6.2)   | 69  | 8.2 (5.6)    | -1.0 (-2.8, 0.8)                      | 0.26 |
| WLQ sub-scales (0-100):                     |      |     |             |     |              |                                       |      |
| - Time demands                              | 0m   | 124 | 35.1 (20.5) | 124 | 35.0 (23.2)  |                                       |      |
|                                             | 6m   | 100 | 31.0 (21.6) | 88  | 28.6 (20.1)  | -2.6 (-8.8, 3.7)                      | 0.42 |
|                                             | 12m  | 98  | 35.5 (25.8) | 91  | 32.1 (24.1)  | -2.7 (-9.0, 3.5)                      | 0.39 |
|                                             | 36m  | 70  | 39.0 (28.1) | 70  | 32.6 (25.5)  | -5.6 (-12.8, 1.5)                     | 0.12 |
| - Physical demands (modified)               | 0m   | 122 | 39.6 (22.1) | 123 | 39.6 (24.1)  |                                       |      |
|                                             | 6m   | 98  | 40.8 (23.9) | 86  | 36.5 (20.9)  | -3.6 (-9.4, 2.2)                      | 0.22 |
|                                             | 12m  | 95  | 41.2 (24.4) | 89  | 36.2 (21.9)  | -4.5 (-10.3, 1.2)                     | 0.12 |
|                                             | 36m  | 69  | 42.9 (26.5) | 69  | 40.3 (27.2)  | -0.4 (-7.0, 6.2)                      | 0.91 |

| Outcome, mean (SD) unless otherwise stated: |                              | Time | n   | Control     | n   | Intervention | Adjusted difference in means (95% CI) | p    |
|---------------------------------------------|------------------------------|------|-----|-------------|-----|--------------|---------------------------------------|------|
| -                                           | Mental-Interpersonal demands | 0m   | 125 | 24.2 (17.7) | 124 | 24.0 (20.3)  |                                       |      |
|                                             |                              | 6m   | 101 | 28.9 (26.1) | 88  | 23.2 (21.8)  | -6.1 (-12.7, 0.4)                     | 0.07 |
|                                             |                              | 12m  | 98  | 27.1 (25.0) | 91  | 26.8 (23.7)  | -0.6 (-7.1, 6.0)                      | 0.86 |
|                                             |                              | 36m  | 70  | 29.0 (25.6) | 70  | 27.2 (22.4)  | -1.9 (-9.5, 5.7)                      | 0.63 |
| -                                           | Output demands               | 0m   | 124 | 30.1 (20.1) | 123 | 29.1 (22.1)  |                                       |      |
|                                             |                              | 6m   | 99  | 32.3 (27.1) | 88  | 26.2 (23.1)  | -5.9 (-13.0, 1.2)                     | 0.10 |
|                                             |                              | 12m  | 98  | 30.8 (26.9) | 91  | 29.4 (25.1)  | -1.7 (-8.7, 5.4)                      | 0.64 |
|                                             |                              | 36m  | 68  | 34.8 (26.9) | 70  | 29.6 (22.2)  | -5.0 (-13.2, 3.2)                     | 0.23 |
| Dual WLQ-25PDmod (0-100)                    |                              | 0m   | 121 | 29.7 (15.4) | 120 | 28.7 (18.0)  |                                       |      |
|                                             |                              | 6m   | 96  | 27.3 (16.6) | 85  | 24.5 (13.5)  | -2.0 (-6.0, 1.9)                      | 0.31 |
|                                             |                              | 12m  | 95  | 27.3 (17.6) | 86  | 26.3 (16.5)  | -1.5 (-5.4, 2.5)                      | 0.46 |
|                                             |                              | 36m  | 65  | 32.1 (20.9) | 68  | 28.9 (18.7)  | -2.7 (-7.1, 1.8)                      | 0.25 |
| WALS-12 (0-36)                              |                              | 0m   | 125 | 12.2 (5.4)  | 124 | 12.0 (5.3)   |                                       |      |
|                                             |                              | 6m   | 101 | 10.8 (5.7)  | 88  | 10.6 (5.3)   | -0.0 (-1.4, 1.3)                      | 0.99 |
|                                             |                              | 12m  | 98  | 11.7 (6.0)  | 91  | 10.7 (5.9)   | -0.9 (-2.2, 0.5)                      | 0.22 |
|                                             |                              | 36m  | 72  | 13.9 (7.3)  | 74  | 11.9 (6.1)   | -1.4 (-3.0, 0.1)                      | 0.07 |
| Dual WALS-12 (0-100)                        |                              | 0m   | 109 | 35.7 (17.2) | 111 | 34.4 (18.0)  |                                       |      |
|                                             |                              | 6m   | 84  | 31.3 (19.2) | 77  | 30.2 (17.1)  | -1.4 (-6.1, 3.3)                      | 0.56 |
|                                             |                              | 12m  | 85  | 33.7 (19.9) | 77  | 31.8 (17.9)  | -1.4 (-6.0, 3.3)                      | 0.56 |

| Outcome, mean (SD) unless otherwise stated:  | Time | n   | Control               | n   | Intervention         | Adjusted difference in means (95% CI) | p    |
|----------------------------------------------|------|-----|-----------------------|-----|----------------------|---------------------------------------|------|
|                                              | 36m  | 59  | 38.4 (21.9)           | 64  | 35.6 (20.8)          | 0.1 (-5.1, 5.3)                       | 0.97 |
| Numbers in employment, n <sup>1</sup>        |      |     |                       |     |                      |                                       |      |
| Full-, part-time, unemployed                 | 0m   | 125 | 69/ 56/ 0             | 124 | 75/49/0              |                                       |      |
|                                              | 6m   | 109 | 61/48/0 <sup>a</sup>  | 107 | 60/46/1 <sup>b</sup> |                                       |      |
|                                              | 12m  | 106 | 56/47/3 <sup>c</sup>  | 98  | 59/37/2 <sup>d</sup> |                                       |      |
|                                              | 36m  | 91  | 44/33/14 <sup>e</sup> | 89  | 49/34/6 <sup>f</sup> |                                       |      |
| Data collected at 0, 6 and 12 m only         |      |     |                       |     |                      |                                       |      |
| WPAI, past 7 days:                           |      |     |                       |     |                      |                                       |      |
| -% work time missed due to health problems   | 0m   | 124 | 5.4 (10.9)            | 116 | 6.1 (13.8)           |                                       |      |
|                                              | 6m   | 100 | 3.4 (10.7)            | 83  | 2.9 (10.7)           | -0.7 (-3.6, 2.1)                      | 0.61 |
|                                              | 12m  | 95  | 2.4 (7.5)             | 87  | 3.4 (9.6)            | 1.0 (-1.9, 3.8)                       | 0.50 |
| -% impairment while working due to health    | 0m   | 124 | 45.9 (22.8)           | 118 | 45.3 (23.5)          |                                       |      |
|                                              | 6m   | 99  | 40.4 (24.9)           | 88  | 43.1 (23.9)          | 2.5 (-3.8, 8.7)                       | 0.44 |
|                                              | 12m  | 96  | 42.0 (25.1)           | 87  | 38.9 (23.2)          | -3.9 (-10.2, 2.4)                     | 0.23 |
| -% overall work impairment due to all health | 0m   | 124 | 47.8 (23.7)           | 116 | 47.6 (24.6)          |                                       |      |
|                                              | 6m   | 99  | 42.0 (25.3)           | 83  | 43.3 (25.3)          | 1.4 (-5.2, 7.9)                       | 0.68 |
|                                              | 12m  | 95  | 43.2 (25.8)           | 87  | 40.4 (24.4)          | -4.4 (-10.9, 2.2)                     | 0.19 |

| Outcome, mean (SD) unless otherwise stated:                  | Time | n   | Control     | n   | Intervention | Adjusted difference in means (95% CI) | p     |
|--------------------------------------------------------------|------|-----|-------------|-----|--------------|---------------------------------------|-------|
| -% activity impairment due to all health                     | 0m   | 125 | 62.8 (22.8) | 124 | 58.1 (25.0)  |                                       |       |
|                                                              | 6m   | 109 | 49.5 (27.8) | 106 | 51.1 (25.3)  | 4.3 (-2.3, 10.9)                      | 0.20  |
|                                                              | 12m  | 104 | 48.8 (26.2) | 97  | 46.2 (25.1)  | 0.4 (-6.4, 7.2)                       | 0.91  |
| <b>0 and 12m only</b>                                        |      |     |             |     |              |                                       |       |
| Absenteeism                                                  |      |     |             |     |              |                                       |       |
| - Participant monthly self-report of number of days off-sick | 6m   | 121 | 10. (23.6)  | 118 | 7.5 (17.0)   | -30% (-64%, 37%) <sup>g</sup>         | 0.30  |
|                                                              | 12m  | 111 | 9.5 (16.9)  | 109 | 8.5 (24.3)   | -46% (-73%, 7%) <sup>g</sup>          | 0.08  |
| RA-WIS (0-23)                                                | 0m   | 125 | 16.2 (4.2)  | 124 | 15.8 (4.6)   |                                       |       |
|                                                              | 12m  | 97  | 14.9 (5.5)  | 90  | 14.4 (5.5)   | -0.3 (-1.5, 0.9)                      | 0.64  |
| Work Self-Efficacy (0-30)                                    | 0m   | 125 | 17.9 (5.3)  | 124 | 18.0 (5.5)   |                                       |       |
|                                                              | 12m  | 102 | 18.4 (6.7)  | 93  | 19.1 (6.)    | 0.4 (-1.0, 1.8)                       | 0.56  |
| <b>Exploratory outcomes:</b>                                 |      |     |             |     |              |                                       |       |
| Satisfaction with work advice received in trial (0-10)       | 6m   | 105 | 7.2 (2.5)   | 102 | 8.7 (1.6)    | -                                     | 0.001 |

Key: <sup>1</sup> Employment status: of those in employment, numbers not attending work due to shielding/ furlough/ sick leave/ authorised leave; at 6m: <sup>a</sup> Control = 6, <sup>b</sup> Intervention = 10; <sup>c</sup> at 12m: Control = 6, <sup>d</sup> Intervention = 6; at 36m, <sup>e</sup> Control = 7; <sup>f</sup> Intervention = 5.

<sup>g</sup> =% relative reduction in sick leave of intervention compared to control group.

RA-WIS; Rheumatoid Arthritis - Work Instability Scale; WALs: Work Activity Limitations Scale; WLQ-25PDmod: Work Limitations Questionnaire-25: Modified Physical Demands scale (i.e. items are not reverse scored)); WPAI Work Productivity Activity Impairment.

728 **Table 3: Health secondary outcome measures**

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| Outcome, mean (SD)                           | Time | n   | Control     | n   | Intervention | Adjusted difference<br>in means (95% CI) | p    |
|----------------------------------------------|------|-----|-------------|-----|--------------|------------------------------------------|------|
| SF-12v2: Physical Component Score<br>(0-100) | 0m   | 125 | 36. (7.5)   | 124 | 36.9 (7.9)   |                                          |      |
|                                              | 6m   | 107 | 37.0 (8.8)  | 102 | 37.8 (8.8)   | 0.1 (-1.8,1.9)                           | 0.94 |
|                                              | 12m  | 101 | 39.7 (9.5)  | 89  | 39.6 (8.8)   | -1.1 (-3.0, 0.8)                         | 0.24 |
| SF-12v2: Mental Component Score<br>(0-100)   | 0m   | 125 | 41.0 (9.1)  | 124 | 41.6 (9.7)   |                                          |      |
|                                              | 6m   | 107 | 44.6 (9.3)  | 102 | 44.1 (9.4)   | -1.0 (-3.3, 1.2)                         | 0.37 |
|                                              | 12m  | 101 | 41.5 (10.1) | 89  | 42.3 (10.1)  | 0.1 (-2.3, 2.4)                          | 0.95 |
| RAID (0-10)                                  | 0m   | 125 | 6.2 (1.7)   | 124 | 5.8 (1.8)    |                                          |      |
|                                              | 12m  | 101 | 5.6 (2.2)   | 89  | 5.3 (1.9)    | 0.1 (-0.4, 0.5)                          | 0.76 |
| RADAI-5 (0-10)                               | 0m   | 125 | 6.1 (1.8)   | 124 | 5.6 (1.8)    |                                          |      |
|                                              | 12m  | 101 | 5.3 (2.1)   | 89  | 5.2 (1.8)    | 0.0 (-0.5, 0.5)                          | 0.87 |

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731 RAID: Rheumatoid Arthritis Impact of Disease; RADAI-5: Rheumatoid Arthritis Disease Activity Index-5; SF-12v2: Short Form 12v2 Health Survey.



733 **Table 4: Contextual factor analysis by group and time**

|                       | N (%)<br>Baseline | Difference between<br>intervention and<br>control (SE) | Adjusted difference in<br>means (95%CI) | P-value for the<br>interaction |
|-----------------------|-------------------|--------------------------------------------------------|-----------------------------------------|--------------------------------|
| Age 12m               | 249               | 0.0 (0.3)                                              | 0.3 (-0.5; 1.1)                         | 0.41                           |
| Age 36m               |                   | -0.2 (0.4)                                             | 0.2 (-0.7; 1.1)                         | 0.73                           |
| Gender 12m:           |                   |                                                        |                                         |                                |
| Male                  | 45                | -11.0 (6.4)                                            | 1.1 (-17.3; 19.6)                       | 0.91                           |
| Female                | 202               | -0.2 (3.2)                                             |                                         |                                |
| Gender 36m:           |                   |                                                        |                                         |                                |
| Male                  |                   | -11.5 (7.8)                                            | 0.4 (-20.1; 20.9)                       | 0.97                           |
| Female                |                   | -1.4 (3.6)                                             |                                         |                                |
| Disease duration 12m: |                   |                                                        |                                         |                                |
| ≤2 years              | 81                | 0.3 (5.0)                                              | -4.2 (-19.6; 11.2)                      | 0.59                           |
| >2 years              | 168               | -2.9 (3.4)                                             |                                         |                                |
| Disease duration 36m: |                   |                                                        |                                         |                                |
| ≤2 years              |                   | 2.0 (5.7)                                              | -8.5 (-25.2; 8.3)                       | 0.32                           |
| >2 years              |                   | -5.4 (4.0)                                             |                                         |                                |
| Comorbidities 12m:    |                   |                                                        |                                         |                                |
| 0                     | 56                | 0.3 (5.6)                                              | 1.6 (-15.3; 18.4)                       | 0.86                           |
| ≥1                    | 193               | -2.7 (3.3)                                             |                                         |                                |
| Comorbidities 36m:    |                   |                                                        |                                         |                                |

|                                             | N (%)<br>Baseline | Difference between<br>intervention and<br>control (SE) | Adjusted difference in<br>means (95%CI) | P-value for the<br>interaction |
|---------------------------------------------|-------------------|--------------------------------------------------------|-----------------------------------------|--------------------------------|
| 0                                           |                   | -6.0 (6.7)                                             | 8.6 (-9.9; 27.1)                        | 0.36                           |
| ≥1                                          |                   | -2.2 (3.7)                                             |                                         |                                |
| SF12v2 Physical Component Score (0-100) 12m | 249               | -0.2 (0.4)                                             | -0.2 (-1.2; 0.7)                        | 0.63                           |
| SF12v2 Physical Component Score (0-100) 36m |                   | -0.2 (0.4)                                             | -0.2 (-1.3; 0.8)                        | 0.67                           |
| SF12v2 Mental Component Score (0-100) 12m   | 249               | 0.2 (0.3)                                              | -0.1 (-0.9; 0.7)                        | 0.85                           |
| SF12v2 Mental Component Score (0-100) 36m   |                   | -0.1 (0.4)                                             | -0.3 ( -1.2; 0.6)                       | 0.45                           |
| RAID-Total (0-10)12m                        | 249               | -0.2 (1.5)                                             | 0.5 (-3.5; 4.5)                         | 0.80                           |
| RAID-Total (0-10) 36m                       |                   | -1.2 (1.8)                                             | -0.5 (-5.0; 4.0)                        | 0.83                           |
| RADAI-5 (0-10) 12m                          | 249               | -1.2 (1.6)                                             | 1.3 (-2.8; 5.4)                         | 0.53                           |
| RADAI-5 (0-10) 36m                          |                   | -1.2 (2.0)                                             | 1.4 (-3.2; 6.0)                         | 0.55                           |
| ONS-Manual Work 12m:                        |                   |                                                        |                                         |                                |
| Non-manual                                  | 133               | 3.3 (3.9)                                              |                                         | 0.27                           |
| Manual                                      | 116               | -7.5 (4.0)                                             | -8.1 (-22.4; 6.2)                       |                                |
| ONS-Manual Work 36m:                        |                   |                                                        |                                         |                                |
| Non-manual                                  |                   | -5.6 (4.3)                                             |                                         | 0.27                           |
| Manual                                      |                   | 0.5 (4.9)                                              | 8.8 (-6.9; 24.4)                        |                                |
| RA-WIS (0-23) 12m:                          |                   |                                                        |                                         |                                |
| Low                                         | 23                | -12.5 (8.5)                                            |                                         |                                |

|                                              | N (%)<br>Baseline | Difference between<br>intervention and<br>control (SE) | Adjusted difference in<br>means (95%CI) | P-value for the<br>interaction |
|----------------------------------------------|-------------------|--------------------------------------------------------|-----------------------------------------|--------------------------------|
| Moderate                                     | 119               | -0.9 (4.1)                                             | 6.4 (-19.3; 32.1)                       | 0.62                           |
| High                                         | 107               | -0.1 (4.2)                                             | -13.5 (-40.8; 13.9)                     | 0.34                           |
| RA-WIS (0-23) 36m:                           |                   |                                                        |                                         |                                |
| Low                                          |                   | 2.2 (9.8)                                              |                                         |                                |
| Moderate                                     |                   | -6.0 (4.5)                                             | 20.0 (-6.0; 46.0)                       | 0.13                           |
| High                                         |                   | 0.6 (5.2)                                              | 6.0 (-22.0; 33.9)                       | 0.67                           |
| Work Self-Efficacy Total (0-30) 12m          | 249               | 0.8 (0.6)                                              | 0.3 (-1.2; 1.7)                         | 0.70                           |
| Work Self-Efficacy Total (0-30) 36m          |                   | -0.3 (0.7)                                             | 0.8 (-2.4; 0.9)                         | 0.40                           |
| Work Demands: Control over Work Schedule 12m |                   |                                                        |                                         |                                |
| Somewhat – a great deal                      | 128               | 2.1 (4.0)                                              |                                         |                                |
| A little – not at all                        | 121               | -5.7 (4.0)                                             | -10.2 (-24.6; 4.1)                      | 0.16                           |
| Work Demands: Control over Work Schedule 36m |                   |                                                        |                                         |                                |
| Somewhat – a great deal                      |                   | -4.8 (4.3)                                             |                                         |                                |
| A little – not at all                        |                   | -0.9 (5.0)                                             | 1.5 (-14.3; 17.2)                       | 0.85                           |
| Work Demands: Job Flexibility 12m            |                   |                                                        |                                         |                                |
| Somewhat – a great deal                      | 94                | -3.0 (4.5)                                             |                                         |                                |
| A little – not at all                        | 155               | -1.0 (3.6)                                             | -4.8 (-19.4; 9.8)                       | 0.52                           |
| Work Demands: Job Flexibility 36m            |                   |                                                        |                                         |                                |
| Somewhat – a great deal                      |                   | -4.1 (4.9)                                             |                                         |                                |

|                                                  | N (%)<br>Baseline | Difference between<br>intervention and<br>control (SE) | Adjusted difference in<br>means (95%CI) | P-value for the<br>interaction |
|--------------------------------------------------|-------------------|--------------------------------------------------------|-----------------------------------------|--------------------------------|
| A little – not at all                            |                   | -2.7 (4.4)                                             | -5.4 (-21.1; 10.4)                      | 0.50                           |
| Work Demands: Ability to Postpone Work Tasks 12m |                   |                                                        |                                         |                                |
| Somewhat – a great deal                          | 64                | 5.7 (5.7)                                              |                                         |                                |
| A little – not at all                            | 185               | -4.4 (3.3)                                             | -9.5 (-26.0; 7.0)                       | 0.26                           |
| Work Demands: Ability to Postpone Work Tasks 36m |                   |                                                        |                                         |                                |
| Somewhat – a great deal                          |                   | -4.1 (6.2)                                             |                                         |                                |
| A little – not at all                            |                   | -3.5 (3.9)                                             | 1.8 (-15.7; 19.4)                       | 0.84                           |
| Work Demands Receive help from colleagues 12m    |                   |                                                        |                                         |                                |
| Somewhat – a great deal                          | 87                | 2.3 (4.9)                                              |                                         |                                |
| A little – not at all                            | 159               | -4.4 (3.5)                                             | -10.8 (-26.0; 4.4)                      | 0.17                           |
| Work Demands: Receive help from colleagues 36m   |                   |                                                        |                                         |                                |
| Somewhat – a great deal                          |                   | 2.7 (5.4)                                              |                                         |                                |
| A little – not at all                            |                   | -7.9 (4.2)                                             | -14.6 (-31.1; 1.8)                      | 0.08                           |
| Work Demands: Physically demanding job 12m       |                   |                                                        |                                         |                                |
| Somewhat – a great deal                          | 125               | -2.0 (4.0)                                             |                                         |                                |
| A little – not at all                            | 124               | -2.0 (4.1)                                             | 4.3 (-10.3; 18.8)                       | 0.57                           |
| Work Demands: Physically demanding job 36m       |                   |                                                        |                                         |                                |
| Somewhat – a great deal                          |                   | -2.7 (4.7)                                             |                                         |                                |
| A little – not at all                            |                   | -2.7 (4.6)                                             | 4.4 (-11.4; 20.2)                       | 0.59                           |

|                                          | N (%)<br>Baseline | Difference between<br>intervention and<br>control (SE) | Adjusted difference in<br>means (95%CI) | P-value for the<br>interaction |
|------------------------------------------|-------------------|--------------------------------------------------------|-----------------------------------------|--------------------------------|
| Work Demands: Mentally demanding job 12m |                   |                                                        |                                         |                                |
| Somewhat – a great deal                  | 232               | -2.4 (2.9)                                             |                                         |                                |
| A little – not at all                    | 17                | 4.8 (10.2)                                             | 3.7 (-24.1; 31.6)                       | 0.79                           |
| Work Demands: Mentally demanding job 36m |                   |                                                        |                                         |                                |
| Somewhat – a great deal                  |                   | -1.3 (3.4)                                             |                                         |                                |
| A little – not at all                    |                   | -30.9 (14.0)                                           | 40.4 (6.7; 75.0)                        | 0.02                           |

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735 Notes: Disease duration ≤2y = early disease, >2y = established disease. Work Demands (5-point Likert scale, re-categorised as a little/ not at  
736 all vs. somewhat/quite a bit/a great deal).

737 ONS: Office for National Statistics; RAID: Rheumatoid Arthritis Impact of Disease; RADAI-5: Rheumatoid Arthritis Disease Activity Index-5; RA-  
738 WIS; Rheumatoid Arthritis - Work Instability Scale; SF-12v2: Short Form 12v2 Health Survey; WALs: Work Activity Limitations Scale; WLQ-  
739 25PDmod: Work Limitations Questionnaire-25: Modified Physical Demands scale (i.e. items are not reverse scored); WPAI Work Productivity  
740 Activity Impairment.

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741 **Table 5: Cost-effectiveness analysis results**

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|                                                     | Control             | Intervention        | Incremental<br>(Intervention – Control) |
|-----------------------------------------------------|---------------------|---------------------|-----------------------------------------|
| Costs                                               | n=106               | n=98                |                                         |
| Intervention cost - Mean (SD)                       | £0 (0)              | £105.77 (55.57)     | £105.77                                 |
| Per person resource use - Mean (SD)                 | £6,565.62 (6781.73) | £6,005.68 (6031.49) | -£559.94                                |
| Total per person costs (unadjusted) - Mean (SD)     | £6,565.62 (6781.73) | £6,113.69 (6034.47) | -£451.93                                |
| Total per person costs (adjusted for previous use)* | -                   | -                   | £346.24                                 |
| QALYs                                               | n=103               | n=92                |                                         |
| Per person QALYs (unadjusted)                       | 0.51                | 0.54                | 0.03                                    |
| Per person QALYs (adjusted for baseline HRQoL)*     | -                   | -                   | -0.003                                  |
| Incremental Net Benefit (INB)                       |                     |                     |                                         |
| Mean** Incremental Net Benefit (pseudo 95% CI) *    | -                   | -                   | -£195.86<br>(-£1,711.54 to £1238.66)    |

\*using imputed data – n=249  
\*\*1000 bootstrapped INB estimates

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744 QALY: Quality Adjusted Life Year.