1   **Five years of patient and public involvement and engagement (PPIE) in the**

2   **development and evaluation of the Pain-at-Work Toolkit to support employees' self-**

3   **management of chronic pain at work.**

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29 **Abstract**

30

31 **Background:** Patient and public involvement and engagement (PPIE) is essential for the

32 design, delivery and dissemination of high-quality, meaningful research. However, reporting

33 of PPIE contributions is seldom transparent or consistent. We aimed to document and

34 critically reflect on the process of embedding robust PPIE throughout every stage of the

35 research cycle in the co-creation and evaluation of the Pain-at-Work (PAW) Toolkit, a digital

36 resource to support working age adults with self-managing chronic pain at work.

37 **Methods:** Using the Guidance for Reporting Involvement of Patients and the Public

38 (GRIPP2-SF) checklist we describe and reflect on PPIE input into four phases of the PAW

39 Toolkit development and testing taking place over five years, all co-led by PPIE-partners,

40 including: (1) Co-Creation: with stakeholder consultation (n=27), surveys with employees

41 (274) and employers (n=107), expert peer review (n=40), (2) Prototype Evaluation: with end-

42 user testing (n=104), end-user interviews (n=15), expert peer reviews (n=15), (3) Review

43 and Update: with a public concept mapping exercise (n=20) and expert peer reviews (n=15),

44 (4) Feasibility Testing: with PPIE-partners (n=2), PPIE-members (n=5), PPIE-contributors

45 (n=10).

46 **Results**: PPIE was successfully embedded at every stage of the research cycle. Our PPIE-

47 partners co-led activities to gather the views diverse stakeholders (PPIE-contributors) such

48 as healthcare professionals, employers, and people with lived experience of chronic pain.

49 We outline 'how' PPIE took place at each phase, and 'who' was involved in each activity. We

50 describe PPIE results in terms of the impact of PPIE on PAW Toolkit development (Phase 1-

51 3) and the research process (Phase 1-4).

52 **Conclusion**: Our PPIE partnerships and shared decision-making led to the co-creation,

53 update and evaluation of the PAW Toolkit, an intervention which is appropriate, meaningful

54 and relevant to working-age adults living with chronic pain. We present components for

55 successful PPIE, and map Pain-at-Work PPIE to recommended components. Components

56 for successful PPIE, challenges and mitigations are reflected upon. PPIE enhanced the

57 'real-world' value of our intervention and methodological rigour of the research processes.

58 Our worked example of PPIE and transferable recommendations could be used to guide

59 other researchers embarking on national or international health research.

60

61 **Trial registration (Phase 4):** ClinicalTrials.gov NCT05838677; registered 01/05/2023

62 https://clinicaltrials.gov/study/NCT05838677

63 **International Registered Report Identifier (IRRID):** DERR1-10.2196/51474

64

65 **Key words:**

66 Public involvement; chronic pain; work; digital; intervention; self-management.

67

68 **Plain English Summary**

69 Patient and public involvement and engagement in research (PPIE) is an essential part of

70 the research process, but PPIE contributions are not always reported in a transparent and

71 consistent way. Here, we present a worked example of how we have embedded PPIE

72 throughout every stage of our research, over a four-year period. Our example is the Pain-at-

73 Work Toolkit, which we designed to support working age adults with self-managing chronic

74 pain at work. The Pain-at-Work Toolkit provides work-related advice and support, such as

75 how to self-manage their pain while at work, and how to access adjustments to their

76 workplace or job role to help them participate in work. We worked together with PPIE-

77 partners to co-create the content and presentation of the Pain-at-Work Toolkit, considering

78 the views of diverse 'stakeholders' described as PPIE-contributors (largely healthcare

79 professionals, employers, and people with chronic pain). This process involved our PPIE-

80 partners co-leading a range of activities, including a public consultation event, two online

81 surveys with people who have pain, and employers, and gathering expert peer reviews of

82 the developed Toolkit. Together with our PPIE-partners, we pilot tested the Toolkit by asking

83 stakeholders and people living with chronic pain to use the Toolkit and share their views in

84 online surveys and interviews. We worked in collaboration with PPIE-partners to use this

85 information to make further updates to the Pain-at-Work Toolkit using a range of methods

86 and approaches. Next, we tested it in a workplace trial, that was co-managed by our PPIE-

87 partner and included 380 people with chronic pain. We have engaged in PPIE throughout

88 the duration of the trial and have two PPIE-partners who are equal members of our research

89 team and co-authors. We have reported our PPIE processes and reflections throughout the

90 five years using the GRIPP2-SF checklist. From what we have learned, we offer practical

91 suggestions for PPIE in future real-world studies.

92

93 **Background**

94

95 It is widely accepted that patient and public involvement and engagement (PPIE) is a vital

96 part of health research [1], since it enhances the relevance, appropriateness, quality, and

97 ethical integrity of research [2, 3]. Public involvement can help to identify the most important

98 research priorities, shape study designs to maximise participation, ensure that research is

99 ethically conducted and that research tools are appropriate, increase recruitment and

100 retention rates, and create more accessible information for research participants [3]. There

101 are mutual benefits, since public contributors report increased confidence, a sense of

102 purpose, and feeling valued [4].

103

104 Most funding bodies expect that PPIE will be integral to the research processes, and they

105 commonly provide infrastructure, support and guidance [5, 6]. While PPIE is known to

106 benefit research, the reporting of PPIE in research has previously been inconsistent, lacking

107 sufficient detail on the process and impact of PPIE [2, 7, 8]. The availability of PPIE reporting

108 guidelines and checklists, such as the Guidance for Reporting Involvement of Patients and

109 the Public (GRIPP-2) [9], has gone some way to increasing consistency in reporting in

110 recent years. However, the level of detail can be sub-optimal. A mixed-methods analysis of

111 current practice in health research publications found that reporting was commonly

112 incomplete, with only 40% of publications reporting the aim of PPIE, and reports on the

113 influence of patients' input being "vague" [10]. Poor quality reporting has been observed

114 even when checklists have been adopted [10] and many researchers report only on PPIE

115 benefits without addressing PPIE challenges [11]. Other researchers have identified a

116 complete absence of PPIE reporting. For example, a study of PPIE in clinical trials published

117 in general nursing science journals identified 89 randomised controlled clinical trials

118 published in 2021, in 27 journals, none of which included any statement or evidence of PPIE

119 [12]. Reporting PPIE in research publications has been described as "the exception and not

120 the rule" [13].

121 There remains a need to enhance the quality of PPIE reporting, providing specific details

122 about *how* and *when* PPIE has been implemented and *by whom*, as well as documenting

123 the *impacts* of PPIE including both benefits and challenges experienced, and how they were

124 managed. This has value for a broad range of stakeholders. Clear reporting ensures that the

125 contributions of public contributors are recognised and valued which could encourage further

126 engagement in research. For researchers, transparent reporting of PPIE not only ensures

127 that studies and interventions are relevant and impactful but may encourage other

128 researchers to engage in high quality PPIE reporting. Higher quality reporting using

129 standardised approaches enhances the credibility and reproducibility of research and

130 therefore creates a stronger evidence base for the influence of PPIE on research processes

131 and outcomes. Improved documentation around PPIE can benefit funders by ensuring that

132 research aligns with public needs. Finally, insights from high-quality PPIE reporting can lead

133 to improved policies and practices, across diverse settings and geographical regions.

134

135 In this paper, we provide a worked example of PPIE implementation and reporting, by

136 documenting and critically reflect on the process of PPIE in the context of workplace health

137 research. We show how collaborative working with members of the public, and shared

138 decision-making, led to the co-creation of the PAW Toolkit, and improved the quality,

139 relevance, and appropriateness of the PAW Toolkit and our research processes.

This work highlights the importance of embedding robust PPIE throughout every stage of the research cycle.

Definitions and terminology

For this study, we use the term 'patient and public involvement and engagement in research' and the acronym PPIE. We adopt the INVOLVE definition of PPIE as research which is "carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them" [14]. Our PPIE occurs at every stage of the research process, from identifying the research question through to influencing policy makers by dissemination of results. We refer to 'PPIE-partners', a mutually agreed term which demonstrates an established and equal partnership with these members of our research team. Having a PPIE-partner confirms our commitment to a collaborative approach in our applied research. Our research programme has included two 'PPIE-partners' (SG, VAF) who have contributed at different stages of our research programme and are considered equal members of the research team. They were recruited through the research team's professional networks. Our PPIE-partners are members of the public with lived experience of chronic conditions and knowledge of the impact of chronic conditions (including chronic pain) on work. One PPIE-partner has held this position throughout Phases 1-4 (VAF), the other through Phases 1-3 (SG). We have 'PPIE-members', who hold positions on our study advisory or steering groups. Our PPIE-partner involved in Phase 1-3 activity transitioned to become PPIE-member in Phase 4. Those supporting involvement or engagement for specific phases or steps within the presented activity (but are not PPIE-partners or PPIE-members) are referred to as 'PPIE contributors' or 'public contributors'. By 'involvement' we refer to research carried out 'with' or 'by' people with lived experience of chronic pain or relevant stakeholders, such as representatives of employing organisations or professional bodies. By 'engagement' we refer to awareness raising, sharing, disseminating knowledge about research, and engaging people with lived experience of chronic pain (not necessarily patients), and other members of the public in a conversation about research.

168

Research Context

The research which is the context for this PPIE activity relates to the development and

evaluation of a digital intervention called the Pain-at-Work (PAW) Toolkit [15, 16]. The PAW

Toolkit aims to support people who have 'chronic or persistent pain' in their place of work

(referred to as 'chronic pain' hereon). The rationale for focusing in this area is that existing

self-management tools for people with chronic pain tend to focus on symptom reporting,

treatment programmes or exercise and do not address barriers to work, facilitators of work

ability, or workplace pain self-management strategies. The PAW Toolkit addresses this

intervention and support gap. The idea for the PAW Toolkit came from a discussion between

the lead author and five working adults who experience chronic pain. These individuals

reported back pain, shoulder pain, knee pain, fibromyalgia, and migraine, and worked in the

public or private sector, three in large organisations and two in small-to-medium sized

enterprises (SMEs). All felt that there was not enough support in the workplace for people

with chronic pain, to help them manage their condition and enjoy a good quality working life.

We discussed possible solutions such as occupational health services and employee

workshops. The former was proposed as one route to providing support, but provision is

inequitable as occupational health services are not available in all employment settings. The

latter was seen to be potentially informative, but employee workshops are time and resource

intensive. There was consensus that a digital toolkit would be the most flexible, accessible

and low resource approach to providing support in different types of workplaces, although a

systematic review showed there were no evidence-based digital resources available at that

time [17].

The PAW Toolkit is fully described elsewhere [15, 16]. It is designed to be relevant to any

employee with chronic pain in any organisation type, size, or sector. The PAW Toolkit offers

evidence-based advice on chronic pain, disability rights, work capacity, pain self-

management strategies, and signposting to support (Figure 1). The theory of change for the

196 PAW Toolkit is: "Providing employees with access to the PAW Toolkit will increase knowledge

197 about employee rights, how to access support for managing a painful chronic condition in

198 the workplace, and lifestyle behaviours that facilitate the management of chronic pain. This

199 in turn will lead to improved self-management of pain at work. The ultimate aim is to improve

200 outcomes for individuals (self-efficacy, work ability, job perceptions, health, and wellbeing)

201 and organisations (presenteeism, absenteeism)" [15, 16].

202

203 **Figure 1.** Pain-at-Work Toolkit sections (Source: [15]).

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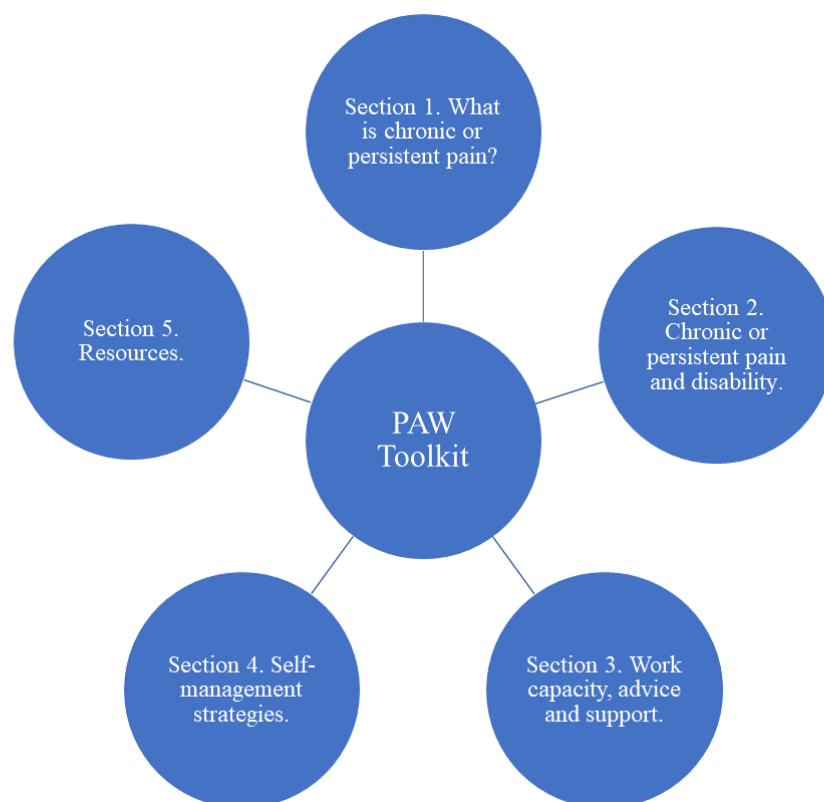
208 **Methodology**

209 Here, we include an overview of all PPIE stages during the development, evaluation and

210 feasibility testing elements of our research programme, describing and reflecting on

211 partnership and shared decision-making with members of the public. Reporting is structured

212   using international evidence based, consensus informed guidance for reporting patient and

213   public involvement in research called GRIPP2-SF [9]; Guidance for Reporting Involvement of

214   Patients and the Public, Version 2, Short-form. The GRIPP2-SF (Additional file 3) aims to

215   improve quality, transparency, and consistency in PPIE reporting and includes five items on

216   (i) aim, (ii) methods, (iii) results, (iv) discussion and conclusions, and (v) reflections/critical

217   perspective.

218

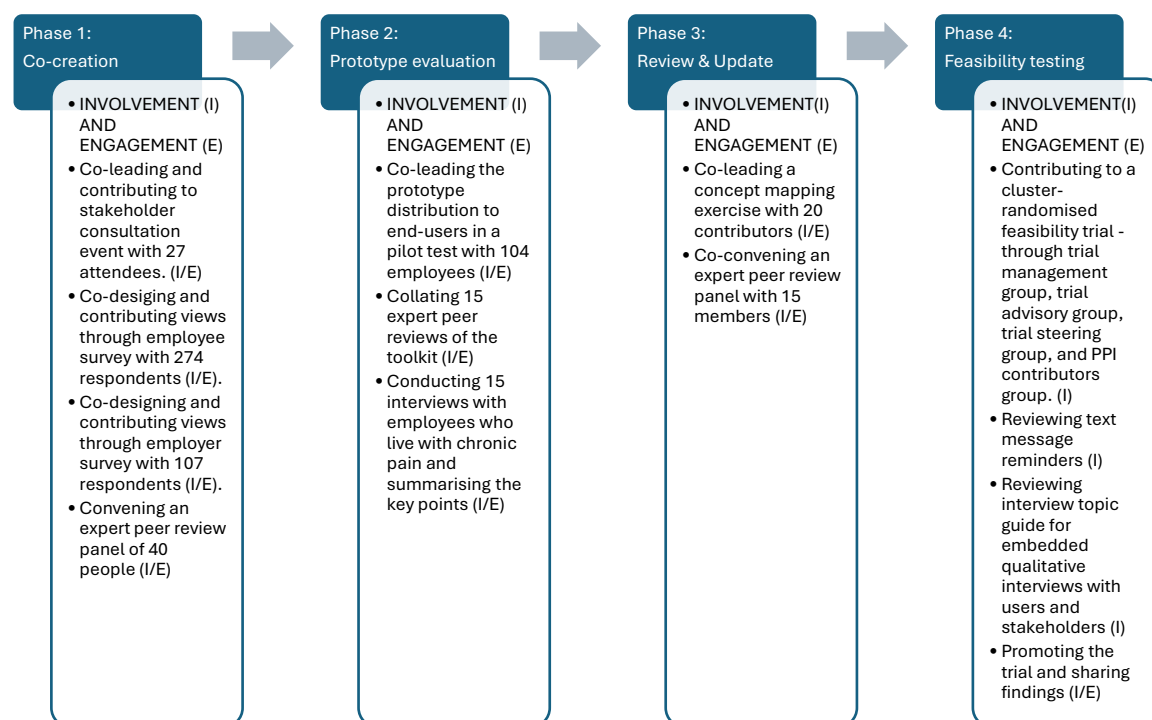219   **Aim of the PPIE**

220

221   In this paper, we aimed to use internationally recognised evidence-based guidance to

222   document and critically reflect on the process of embedding robust PPIE throughout every

223   stage of the research cycle in the co-creation and evaluation of the PAW Toolkit, a digital

224   resource to support working age adults with self-managing chronic pain at work. The

225   purpose of the PPIE input into our research programme was to co-create the PAW Toolkit,

226   and to improve the quality, relevance, and appropriateness of the PAW Toolkit and our

227   research processes to our target population - working age adults with chronic pain.

228   We aimed to reflect on components for successful PPIE, challenges and mitigations, and

229   provide a worked example of PPIE and transferable recommendations that can be used to

230   guide other researchers embarking on national or international health research.

231

232   **Methods of the PPIE**

233   The four phases of the PAW Toolkit development and testing included: 1. Co-creation, 2.

234   Prototype Evaluation, 3. Review and Update, and 4. Feasibility Testing. Our PPIE activity

235   occurred across all four phases - Figure 2 identifies the public involvement and/or

236   engagement at each stage, identifying where members of the public have co-designed, co-

237   led and contributed to activities within each phase. Further details of the research context,

238   including the intervention's theoretical underpinning, content, and presentation, and all

239   processes involved in the co-creation, update and testing of the PAW Toolkit, are reported

240   elsewhere [15, 16, 18]. For each phase we describe the purpose, who was involved and the

241   approaches taken.

242

243   **Figure 2.** Four phases of PPIE

Phase 1: Co-creation	Phase 2: Prototype evaluation	Phase 3: Review & Update	Phase 4: Feasibility testing
• INVOLVEMENT (I) AND ENGAGEMENT (E) • Co-leading and contributing to stakeholder consultation event with 27 attendees. (I/E) • Co-desiging and contributing views through employee survey with 274 respondents (I/E). • Co-designing and contributing views through employer survey with 107 respondents (I/E). • Convening an expert peer review panel of 40 people (I/E)	• INVOLVEMENT (I) AND ENGAGEMENT (E) • Co-leading the prototype distribution to end-users in a pilot test with 104 employees (I/E) • Collating 15 expert peer reviews of the toolkit (I/E) • Conducting 15 interviews with employees who live with chronic pain and summarising the key points (I/E)	• INVOLVEMENT(I) AND ENGAGEMENT (E) • Co-leading a concept mapping exercise with 20 contributors (I/E) • Co-convening an expert peer review panel with 15 members (I/E)	• INVOLVEMENT(I) AND ENGAGEMENT (E) • Contributing to a cluster-randomised feasibility trial - through trial management group, trial advisory group, trial steering group, and PPI contributors group. (I) • Reviewing text message reminders (I) • Reviewing interview topic guide for embedded qualitative interviews with users and stakeholders (I) • Promoting the trial and sharing findings (I/E)

244

245   *Phase 1 Co-Creation*

246   The purpose of Phase 1 was for the researchers to work in partnership with members of the

247   public to co-create the PAW Toolkit content, technical presentation and delivery approach.

248   We used an agile approach to digital intervention development, which the lead author has

249   used previously in the development of digital interventions in the context of work and health

250   [7, 19-21]. Phase 1 involved 4 steps of PPIE activity [16], and five co-authors were involved

251   in each step within this phase (HB, SS, WJC, SG, VAF). In Step 1, a PPIE-partner co-led a

252   stakeholder consultation workshop with 27 attendees. In Step 2, PPIE-partners and the

253   researchers co-designed a stakeholder survey through which 274 working adults

254   ('employees') with chronic pain (PPIE-contributors) shared their views. In Step 3, PPIE-

255 partners and the researchers co-designed a second stakeholder survey through which 107

256 employer representatives from 45 small-to-medium sized organisations and 62 large

257 organisations (PPIE-contributors) shared their views. In Step 4, a PPIE-partner convened a

258 peer review panel of 40 stakeholders.

259 Step 1, the stakeholder consultation workshop was a 2-hour face-to-face event, held on 04

260 February 2020 in a room at a higher education institution, in England. Stakeholder

261 consultation workshops are common method for gathering input and feedback from

262 members of the public for intervention co-production, as part of a wider approach to PPIE

263 [22]. The purpose of the event was for 'stakeholders' (e.g., health professionals, employers

264 and members of the public with lived experienced of chronic pain) to share their views about

265 the type of content they would value, and what format they would prefer it in The event

266 involved a presentation about the topic area (chronic pain self-management) and the

267 concept (a digital toolkit) delivered by the lead author (HB). This was followed by discussion

268 and small group activities, facilitated by the project researchers (HB/SS – full room

269 discussion; WJC – group activities), and PPIE-partner (SG – group activities). In total,

270 twenty-seven public contributors attended the consultation. Their characteristics, expertise

271 and PPIE contributions are shown in Figure 3, which highlights areas of shared decision-

272 making. At attendees' request, these demographics are documented at group level to protect

273 confidentiality of those public contributors who had disclosed chronic pain conditions.

274

275 **Figure 3.** Phase 1 PPIE consultation: stakeholder backgrounds and contributions

Professional expertise	Attendee characteristics	PPIE contribution
• Lived experience of pain • Nursing • Pain management • Pharmacy • Rehabilitation • Occupational health • Physiotherapy • Human resource management • Trade union • Local council • Health psychology • Public health • Workplace wellbeing • Welfare • Equality, diversity and inclusion • Ergonomics • Human factors • Digital health • Educational interventions	• Diverse lived experience of chronic pain: back pain, arthritis, complex regional pain syndrome, multiple sclerosis, neuropathy, irritable bowel, headache and migraine, fibromyalgia, diabetes or cancer-related pain • Diverse sociodemographic characteristics: age, gender, educational level, occupation and pain-related experience, nationality, ethnicity and cultural group	• Establishing the research need • Agreement on a single digital intervention suitable for all worker types, in all employment settings, and with any condition • Establishing consensus on the intervention format and delivery approach • Co-creation of toolkit content • Co-creation of ideas for toolkit format and technical presentation • Contribution to outline dissemination plan for the developed toolkit. • Commenting on and revising Phase 1 employee and employer survey questions

276

277 The remainder of PPIE activity for Phase 1 was conducted during the coronavirus (COVID-

278 19) pandemic which occurred between 11 March 2020 and 05 May 2023. As such, all other

279 activities were conducted remotely, and the project timelines were extended.

280

281 In steps 2 and 3, two PPIE contributors (VAF/SG), co-designed and undertook two online

282 surveys together with members of the research team (HB/SS) to gather views and

283 suggestions from working adults with chronic pain (step 2), and employer representatives

284 from different types and sizes of organisation (step 3). According to the National Institute for

285 Health and Care Research Applied Research Collaboration East Midlands [22], surveys are

286 commonly used and time-efficient PPIE advisory method, to gather opinions and

287 perspectives to shape research – in this case, toolkit development. Potential public

288 contributors could access the questions through a link to an online survey which was

289 circulated on social media, and via professional networks (by HB, SS, VAF, SG).

290   Employees were asked to share their support needs and suggest how employers might

291   meet these needs; employers were asked about the best ways to support people with

292   chronic pain at work and to share resources and materials that could be included in a toolkit.

293   Views were gathered between 02 March – 30 April 2020; due to the pandemic, the employee

294   survey was then re-opened for a further three months between 01 October 2020 – 31

295   December 2020 to provide opportunity to gather further views. As public contributors, a total

296   of 274 employees, and 107 employer representatives shared their views. Full details are

297   reported in [16]. Suggestions were pooled and summarised by team members working in

298   partnership (researchers: HB, SS; PPIE-partners: SG, VAF) to inform toolkit content

299   development.

300   Step 4, the expert peer review for Phase 1, was undertaken between 01 October 2020 and

301   30 November 2020 (iteratively, as per Agile approach). In this step, PPIE-partners (SG, VAF)

302   and researchers (HB, SS) convened an expert peer review panel of 40 stakeholders. These

303   individuals were identified by the research team with input from PPIE-partners. They were

304   chosen for their expertise in chronic pain and disability, work and health, or digital health

305   interventions. They included healthcare professionals, employer representatives, and people

306   with lived experienced of chronic pain. These 40 public contributors reviewed the draft toolkit

307   content and made suggestions for revision, materials to include, and presentation to ensure

308   the toolkit met accessibility guidelines. Further details about Phase 1, including specific

309   detail about changes made to the toolkit during this time, are reported elsewhere [16].

310   Overall, Phase 1 resulted in a co-created prototype toolkit by 31 December 2020, ready for

311   testing and evaluating. All processes in Phase 1 involved working in direct partnership with

312   our PPIE-partners, who engaged in shared decision-making with the research team and

313   helped to gather the views of diverse stakeholders to inform intervention development.

314

315   *Phase 2 Prototype Evaluation*

316   The purpose of this phase was to evaluate the prototype toolkit. This activity took place

317   between 01 September 2021 and 31 December 2021. Three co-authors were involved in

318   Phase 2, including one researcher (HB) and two PPIE-partners (SG, VAF). The process

319   involved prototype distribution, collating feedback through an online evaluation survey,

320   qualitative interviews and expert peer review. Surveys and interviews are described as

321   commonly used PPIE advisory methods in the UK [22]. The process was co-led by our

322   PPIE-partner (SG) who gathered and summarised evaluation feedback and conducted the

323   evaluation interviews with supervision and training from the lead author (HB).

324

325   Over a 12-week period, the team (researcher: HB; PPIE-partners: VAF, SG) released the

326   web link to the prototype toolkit together with a link to an online evaluation feedback form

327   (Additional file 2). To gather feedback from as diverse a group of public contributors as

328   possible, these links were made accessible to people with lived experience of chronic pain

329   and professionals with expertise in pain management or work and health ('expert peer

330   reviewers'). Public contributors were able to get involved through information shared via

331   national charities, professional networks, community group newsletters, and social media (*X*

332   (formerly Twitter), Facebook, LinkedIn). Fifteen professionals agreed to be 'expert peer

333   reviewers' and share their views – they had expertise in human resource management,

334   occupational health, physiotherapy, nursing, and pain research. One hundred and four

335   working adults who self-identified as living with chronic pain shared their views. To do this,

336   all completed the online feedback form. They were 84% female, 11% male, 5% non-binary

337   and identified with 11 different ethnic groups (Additional file 3).

338

339   Thirty of the 104 individuals with lived experience of chronic pain agreed to take part in an

340   interview (with PPIE-partner SG). Of these, 15 were able to find a convenient date and time

341   to do this between 01 October 2021 – 31 December 2021. The primary purpose of the

342   interviews was to provide a space for public contributors to share more in-depth views on the

343   relevance, usability and utility of the PAW Toolkit. However, this also provided an opportunity

344   for our PPIE-partner (SG) to gain professional experience of leading a PPIE activity.

345   Interview discussions ranged from 18 to 41 minutes (mean: 31 minutes). The 15 public

346   contributors with lived experience of chronic pain included 12 women and 3 men, identifying

347   as White/British (n=14) and White/European (n=1). They were aged between 18 and 64

348   years (18-24: n=1; 25-34: n=4; 35-44: n=1; 45-54: n=7; 55-64: n=2). The number of years

349   they had experienced chronic pain varied from 2-35 years (2-3 years: n=3; 4-6 years: n=5; 8-

350   15 years: n=3; 21-35 years: n=4). One of the public contributors was on long-term sick

351   leave, six were working full-time, and seven were working part-time. These individuals

352   worked in the private sector (n=5), public sector (n=8) and third sector (n=1). Two were self-

353   employed, two were employed in medium-sized organisations (50-250 staff) and 10 were

354   employed in large organisations (>250 staff).

355   Our PPIE-partner (SG) summarised the key points within the interview discussions. These

356   were finalised through discussion between two team members (researcher: HB; PPIE-

357   partner: SG), and direct quotes from public contributors were extracted to support and

358   illustrate key points.

359

360   Overall, Phase 2 evaluation surveys (from people living with chronic pain, and expert peer

361   reviewers) and interviews (with people living with chronic pain) provided key insights from

362   public contributors which informed updates to the prototype PAW Toolkit. All processes in

363   Phase 2 involved working in direct partnership with our PPIE-partner, who engaged in

364   shared decision-making with the research team and helped to gather the views of diverse

365   stakeholders to refine the PAW Toolkit prototype.

366

367   *Phase 3 Review and Update*

368   The COVID-19 pandemic led to a delay between PAW Toolkit completion [16] and its testing

369   in a feasibility trial [15]. The toolkit was developed in 2020 and evaluated in 2021 (Phases 1

370   and 2) and we therefore added additional PPIE activity to ensure the toolkit remained fit-for-

371   purpose post-pandemic. The purpose of Phase 3 was therefore to ensure that content

372   remained relevant and up to date, and undertake any updates required (Phase 3).

373   Phase 3 PPIE was conducted in two steps [18]: (1) A concept mapping exercise involving 20

374   public contributors occurring in 2022, (2) Expert peer review involving five public contributors

375   occurring in 2022 and 2023.

376   In step one, a rapid and pragmatic group concept mapping process was undertaken on 14

377   July 2022, to integrate perspectives of a range of stakeholders with differing experiences

378   and expertise to re-affirm content priorities, update and refine the PAW Toolkit ready for

379   testing in a feasibility trial. This step was co-led by our PPIE-partners (VAF, SG) working

380   together with researchers (HB, SS). Concept mapping is a structured conceptualisation

381   process involving multiple stages: preparation, brainstorming, sorting, rating, and

382   interpretation. It is a commonly used tool for public health intervention development, allowing

383   for the integration of practical and scientific knowledge with stakeholders representing

384   different perspectives, the documentation of programme elements and how they relate to

385   one another, and the identification of priorities [18, 23, 24]. This activity was hosted online in

386   a scheduled slot within an educational event on "Work and Health" being delivered by the

387   lead author (HB). The 20 attendees were public contributors ('stakeholders') who were

388   employees with chronic pain, managers, trade union representatives, human resource and

389   occupational health specialists, university researchers and healthcare professionals. All

390   these public contributors were involved in review of the theory of change, generation of

391   statements, sorting, and rating. Six of the public contributors were subsequently involved in

392   mapping and 'interpretation' at a follow-up online validation meeting, one week later.

393

394   'Preparation' occurred prior to the session (between 07 July 2022 and 13 July 2022) and

395   involved the 20 public contributors reviewing the PAW Toolkit accessed via a web link, and

396   theory of change statement (see 'Research context'); both of which were perceived to be

397   appropriate, relevant and useful. 'Brainstorming' took place during the first online session. It

398   involved using free-text responses from the 274 employee survey responses gathered in

399   Phase 1 [16] from which the group generated 102 statements indicating the education and

400   support priorities of people with pain with specific relation to the workplace. After removal of

401   repetition, 78 statements remained. During 'Sorting' and 'Rating', the 20 public contributors

402   individually sorted statements into meaningful groupings and rated them in terms of

403   perceived importance, and confidence that a web-based toolkit could address each (using 5-

404   item Likert scales: 'importance' and 'confidence'). Categorisation of the statements

405   demonstrated that they all directly aligned with five 'clusters' which constituted the five

406   sections of the PAW Toolkit shown in Figure 1. Insights gathered from this group concept

407   mapping exercise, co-led with PPIE-partners, were used by the research team to support the

408   refinement and updating of the PAW Toolkit. Core sections from the original prototype

409   aligned with the concept mapping outcome and were retained, while section content was

410   updated to reflect current views of members of the public and other stakeholders. Full details

411   of this approach have been published elsewhere [18].

412

413   In step 2, the research team gathered feedback from five expert peer reviewers between 10

414   December 2022 and 15 March 2023, to ensure the content remained relevant in 2023. This

415   process was co-led by our PPIE-partner (VAF) and the lead author (HB) who identified

416   appropriate reviewers and helped to collate feedback. The peer reviewers included three

417   people who lived with chronic pain, and two people with professional expertise in workplace

418   health and wellbeing, specifically, support for people with chronic pain (occupational health

419   specialist, workplace physiotherapist). This process involved online discussion via video-

420   conferencing platform and/or feedback provided via email correspondence.

421

422   In summary, Phase 3 PPIE [18] confirmed the validity of the original theory of change and

423   the appropriateness of the PAW Toolkit sections and content. These vital public contributions

424   led to minor revisions to the PAW Toolkit to correct any broken links and add some new

425   information to the additional resources section. At the end of Phase 3, the PAW Toolkit was

426   considered ready for testing in a feasibility trial. Through co-leadership of Phase 3 activities,

427   we demonstrate how our PPIE-partners were involved in shared decision-making relating to

428   the toolkit development and refinement.

429

Phase 4 Feasibility Testing

The purpose of this phase is to ensure that members of the public and relevant stakeholders contribute to the design, processes and dissemination within an externally funded cluster-randomised workplace trial [15]. The aim of the trial was to examine the feasibility and acceptability of the PAW Toolkit with employees who live with chronic pain, in different types of employment settings. The trial opened on 01 March 2023, and recruitment is now complete. From 18 organisations taking part in the trial, 380 employees with chronic pain were recruited. PPIE is embedded at every stage of the research from development, to testing in a trial, dissemination, and informing future research. Six co-authors have been involved in the PPIE in Stage 4. These individuals are researchers who have planned and coordinated PPIE input to the project (HB, EW, WJC, KWB), a PPIE-partner (VAF) who has led trial-related PPIE activity, and the remaining two co-authors have contributed in an external advisory capacity through the Trial Advisory Group (TAG) (PPIE-partner: SG) and Trial Steering Group (TSG) (researcher: SS). Our PPIE-partner (VAF) sits on our Trial Management Group (TMG) and provides advice to the study team as an equal partner. During the trial design stage, members of the research team (HB and EW) consulted with 10 PPIE-contributors from across two Versus Arthritis Pain Centres in the UK who reviewed our study materials at the outset (e.g., participant information sheets, protocol, recruitment plans, study summaries) and shared their views on best approaches to recruit and retain organisations and employees. Five PPIE-contributors reviewed additional study materials (e.g., our interview topic guides and text message reminders). Our PPIE-partner (VAF) has contributed to dissemination of study information on social media, through professional networks and charity websites, and worked together with the research team to disseminate project information through national public-facing events such as the "Burning Nights Patient and Carers Conference 2024" (host: VAF; invited speaker: HB; group facilitator: WJC). Our TAG consists of a group of public contributors who represent organisations with a vested interest in research, policy and/or practice in work and health, digital innovations, or

457   chronic conditions management. The TAG includes four people with lived experience of

458   chronic pain (plus PPIE-partner VAF) who review and guide us on our trial processes,

459   research materials, dissemination and communication plans. Our TSG includes one PPIE-

460   member with lived experience of chronic pain who contributes to oversight of trial

461   procedures and quality assurance. PPIE-members of TAG and TSG preferred not to be

462   identified in a manuscript as individuals with chronic pain.

463   Overall, the PPIE input through Phase 4 ensures that our research processes and materials

464   are meaningful, relevant, and low burden, and our intervention remains fit-for purpose. All

465   processes in Phase 4 have involved collaboration and shared decision-making with our

466   PPIE-partner (VAF). This feasibility trial ends in November 2025 and will provide insights into

467   the acceptability of the toolkit, people's views towards it, and how people used it in the

468   context of work. Our learning from Phase 4 PPIE activity will subsequently inform how we

469   engage and work with PPIE-partners, PPIE-members, and PPIE-contributors in the design

470   and delivery of a future definitive trial, and the future scale up and sustainability of our

471   intervention.

472

473   *Ethical considerations*

474   As UK-based PPIE and intervention development activity, ethical approval was not required

475   and since PPIE contributors are not research participants they are not required to give

476   formal written consent for their involvement. The PPIE activities in the creation and

477   evaluation of the PAW Toolkit (Phases 1-3) did not require research ethics approval as they

478   were classified as public consultation and educational development by the University of

479   Nottingham Faculty of Medicine and Health Sciences Research Ethics Committee (Ref:

480   FMHS 358-0921; 08 Jan 2020 and 27 September 2021). The same committee subsequently

481   granted research ethics approval for the PAW Toolkit feasibility trial (Ref: FMHS 237-0323;

482   31 March 2023) – although ethical approval is not required for PPIE activity, this trial

483   approval does include our Phase 4 PPIE plans.

484 As good practice, across Phases 1-4, our PPIE-partner and public contributors were made

485 aware of the nature of their involvement, their right to withdraw when they wish, any

486 implications and risks of being involved. For synchronous PPIE activity, including the Phase

487 1 stakeholder consultation event and the Phase 3 concept mapping exercise, two

488 researchers (HB, SS) documented 'informed verbal consent' for synchronous activity in the

489 presence of the group. For asynchronous PPIE activity 'informed assumed consent' was

490 taken, including Phase 1 anonymous online PPIE surveys with public contributors

491 (employees/employers) and expert peer review (public contributors/stakeholders), Phase 2

492 expert peer review, and anonymous PPIE evaluation feedback surveys with PAW Toolkit

493 users, and Phase 3 expert peer review. For Phase 2, our PPIE-partner (SG) gathered

494 'informed written consent' from public contributors sharing their views in interviews. In Phase

495 4, while our PPIE-partner provided verbal consent, written consent is not required as she is

496 considered an equal member of the research team.

497

498 **Results of the PPIE**

499 Here, we outline PPIE input at each stage within the research cycle (Phase 1-4) and who

500 was involved in each activity. We describe the impact of PPIE on PAW Toolkit development

501 (Phase 1-3) and the impact of PPIE on the research process (Phase 1-4).

502

503 *PPIE input within the research cycle*

504 Here, we describe the ways in which our stakeholders and PPIE-partners, PPIE-members

505 and PPIE-contributors have contributed at every stage of the research cycle (Table 3), at all

506 stages overseen by the lead author (HB) and supported by the broader research team.

507 There were no unsuccessful *routes* to PPIE engagement in this programme of work,

508 although *challenges* in PPIE engagement are reflected upon in the discussion.

509

510 **Table 3.** PPIE contributions through the research cycle

Research stage	Route to public involvement and engagement	Who was involved?
Phase 1: Co-creation		
Conception: Establishing the support need	Individual consultation Online employer survey Online employee survey	Partners[a,b]/Contributors Partners[a,b]/Contributors Partners[a,b]/Contributors
Conception: establishing the medium as stand-alone / digital	Individual consultation Stakeholder consultation workshop	Partner[a]/Contributors Partner[b]/Contributors
Establishing the theory of change	Individual consultation	Partner[a]/Contributors
Co-creation of content and technical presentation	Individual consultation Stakeholder consultation workshop Expert peer review	Partners[a,b]/Contributors Partner[b]/Contributors Partners[a,b]/Contributors
Role in stakeholder workshop delivery	Stakeholder consultation workshop	Partner[b]/Contributors
Role in sourcing other PPIE reviewers	Expert peer review	Partners[a,b]/Contributors
Phase 2: Prototype evaluation		
Exploring views of people with chronic pain towards the PAW Toolkit	Employee survey with toolkit users	Partner[b]/Contributors
Exploring views of professionals with an interest in pain at work, towards the PAW Toolkit	Expert peer review survey with toolkit users	Partner[b]/Contributors
Gathering in-depth insights from people with chronic pain towards their needs at work, and the potential supportive role of the toolkit	Interviews with employees who have chronic pain	Partner[b]/Contributors
Update and refinement of content and technical presentation	Group concept mapping exercise Expert peer review	Partners[a,b]/Contributors Partners[a,b]/Contributors
Ensuring adherence to equality, diversity and inclusion principles	Employee survey with toolkit users Expert peer review survey with toolkit users Toolkit evaluation interviews with employees who have chronic pain	Partners[a,b]/Contributors Partners[a,b]/Contributors Partners[a,b]/Contributors
Phase 3: Review and update		
Review and confirmation of the theory of change	Group concept mapping exercise	Partners[a,b]/Contributors
Confirmation of the priorities of people with chronic pain at work and appropriateness of toolkit subsections.	Group concept mapping exercise	Partners[a,b]/Contributors
Refinement of content and technical presentation	Group concept mapping exercise Expert peer review	Partners[a,b]/Contributors Partners[a,b]/Contributors

Ensuring adherence to equality, diversity and inclusion principles	Expert peer review	Partners[a,b]/Contributors
Phase 4: Feasibility testing		
Finalising the study design	Individual consultation	Partner[a]/Contributors
Review of protocol and study materials: information sheets, posters, promotional messaging, questionnaires, interview topic guides.	Individual consultation, review and revision	Partner[a]/Contributors
Input into public-facing web materials	Study promotion adverts Project website	Partner[a]/Contributors
Study promotion (web / social media)	Social media posts (e.g., X (formerly Twitter), LinkedIn)	Partner[a]/Members[b]
Advice on routes for recruitment of organisations	Individual consultation (email/meetings) Trial Management Group Trial Advisory Group	Partner[a]/Members[b] Partner[a] Partner[a]/Members[b]/Contributors
Advice on plans for maximising employee uptake	Individual consultation Trial Management Group Trial Advisory Group	Partner[a]/Contributors[b] Partner[a] Partner[a]/Members[b]/Contributors
Development and review of a series of text message reminders for trial participants	Individual consultation (email/meetings)	Partner[a]/Contributors
Review of written description of opt-in OT support	Individual consultation (email/meetings)	Partner[a]
Membership of Trial Management Group	PPIE-partner attendance at monthly meetings	Partner[a]
Membership of Trial Steering Group	PPIE-member attendance at 6-monthly meetings	Members[a]
Membership of Trial Advisory Group	PPIE-partner and PPIE contributors' attendance at 3-monthly meetings	Partners[a,b]/Members[b]/Contributors
Project reporting (development work, and feasibility trial)	Individual consultation	Partners[a,b]/Members[b]
Research dissemination	Co-authorship of conference outputs Co-authorship of research articles Joint dissemination at national PPIE events (e.g., Patients and Carers Conference)	Partners[a,b] Partners[a,b] Partner[a]
PPIE involvement dissemination	PPIE-partner's presentation at a National Pain Centre PPIE event at the host university Co-authorship of PPIE case study submitted to a national pain charity	Partner[a] Partner[a]

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From the authorship team: [a]PPIE-Partner VAF; [b]PPIE-partner / PPIE-member / PPIE-contributor SG. Note changes to roles in different study phases and over time. PPIE-members and PPIE-contributors are a broader group of members of the public (including stakeholders and people with lived experience of chronic pain) and are not identified individually except for co-author SG.

516 *Impact of PPIE on PAW Toolkit development*

517 The final version of the toolkit was co-created in Phases 1-3 (Figure 1), more details can be

518 found elsewhere [15, 16]. Phase 2 evaluation feedback from the public contributors is

519 provided below, for the expert reviewers (Table 1) and working people living with chronic

520 pain (Table 2).

521

522 **Table 1.** PAW Toolkit Phase 2 expert reviewer evaluation (n=15)

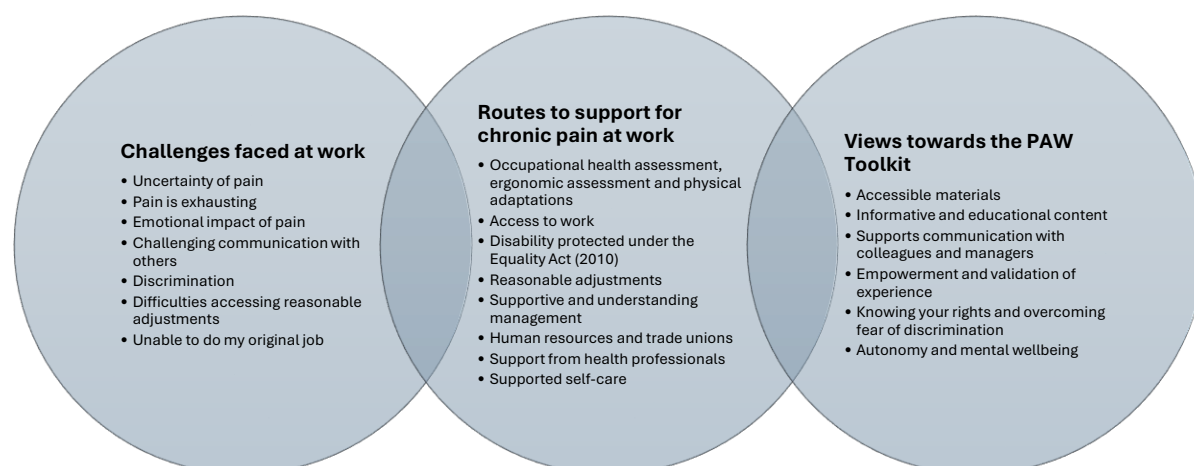| Review Question	Yes / n(%)
Is the focus of the resource clear and consistent?	13 (87)
To your knowledge is the information factually correct?	14 (93)
Is the text well written and in short, clear sentences?	13 (87)
Do the suggested links provide the information needed?	14 (93)
Are the broad sections appropriate?	15 (100)
Is the overall presentation appropriate? (e.g. layout, images, links?)	15 (100)
How easy is this resource to access via the link?	15 (100)
Could this be accessed in different settings (e.g. workplace / home)?	15 (100)
Is this package relevant to any employee who has chronic pain?	13 (87)

523

524 **Table 2.** PAW Toolkit Phase 2 public contributor evaluation (n=104)

Question (yes/no)	Yes / n(%)
Were you able to access a fully functioning toolkit?[a]	100 (96)
Did you understand the information provided in this toolkit?	101 (97)
Have you gained sufficient knowledge from this resource?	84 (81)
Have you practically used any of the information?[b]	52 (50)
If you have not yet practically used the information, could it have future value for you?	99 (95)
Could this toolkit resource be used by any employee who has chronic pain?	100 (96)
Was engaging with this toolkit time well spent?	96 (92)
Was using this toolkit challenging with regards to your own digital skills?	3 (2)
Did you experience any technical difficulties in using this toolkit?[c]	8 (7)
Was this package appropriate for your needs?	93 (89)
Did this resource contain meaningful information?	103 (99)
Would you recommend this package to a colleague?	100 (96)
Question (score 1-10)	**Range, Mean**
Was this resource easy to navigate and use? (1= not at all easy, 10 = extremely easy)	4-10, 8.8
How do you feel about this resource being available for people who have chronic pain? (1=very negative, 10=highly positive)	4-10, 9.0
How relevant is this toolkit to people who have chronic pain?[d] (1=not at all relevant, 10 = extremely relevant)	1-10, 8.4

525 Notes: [a]Those responding 'no' reported an employer firewall which blocked access, or mobile phone signal issues. [b]PAW Toolkit
526 prototype and the evaluation survey were distributed at the same time. [c]Reported technical difficulties included lack of sound on
527 their own computer/device, an employer firewall which blocked access, or malfunctioning links. [d]Reasons for lack of relevance
528 primarily related to (1) existing knowledge and good workplace support, (2) not being employed.

529

530 Our PPIE-partner (SG) categorised key points from the interview discussions with public

531 contributors into three broad areas (Figure 4): (1) The challenges faced at work, (2) Support

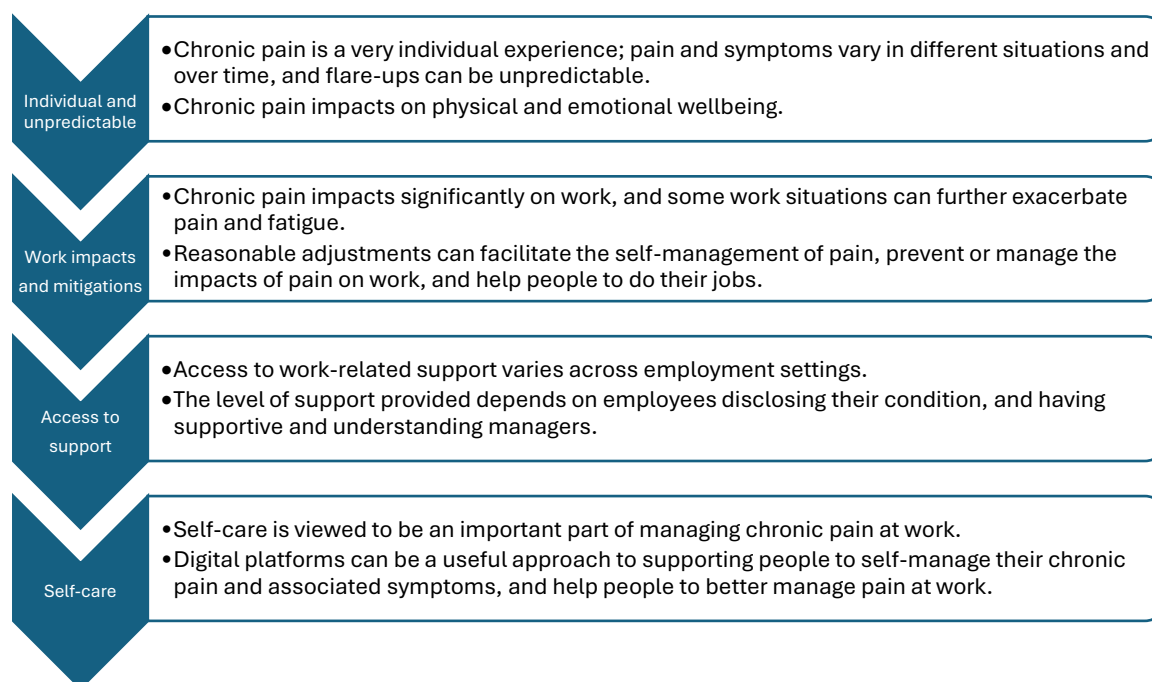532 accessed in the workplace to manage work alongside pain, (3) Views towards the toolkit.

533

534 **Figure 4.** Public contributors' key points drawn from toolkit evaluation interviews

Challenges faced at work
- Uncertainty of pain
- Pain is exhausting
- Emotional impact of pain
- Challenging communication with others
- Discrimination
- Difficulties accessing reasonable adjustments
- Unable to do my original job

Routes to support for chronic pain at work
- Occupational health assessment, ergonomic assessment and physical adaptations
- Access to work
- Disability protected under the Equality Act (2010)
- Reasonable adjustments
- Supportive and understanding management
- Human resources and trade unions
- Support from health professionals
- Supported self-care

Views towards the PAW Toolkit
- Accessible materials
- Informative and educational content
- Supports communication with colleagues and managers
- Empowerment and validation of experience
- Knowing your rights and overcoming fear of discrimination
- Autonomy and mental wellbeing

535

536 Further detail about public contributors' challenges experienced at work, their description of

537 current routes to accessing support in the workplace and illustrative quotes can be found in

538 Additional file 4; these provide the broader contexts of lived experiences in this group that

539 help to inform what types of support the PAW Toolkit needs to provide. Directly aligned with

540 the aim of our PPIE, our PPIE-partner (SG) collated the views of public contributors towards

541 the content, presentation and usability of the PAW Toolkit (as summarised in Figure 4) which

542 are expanded upon in Additional file 5.
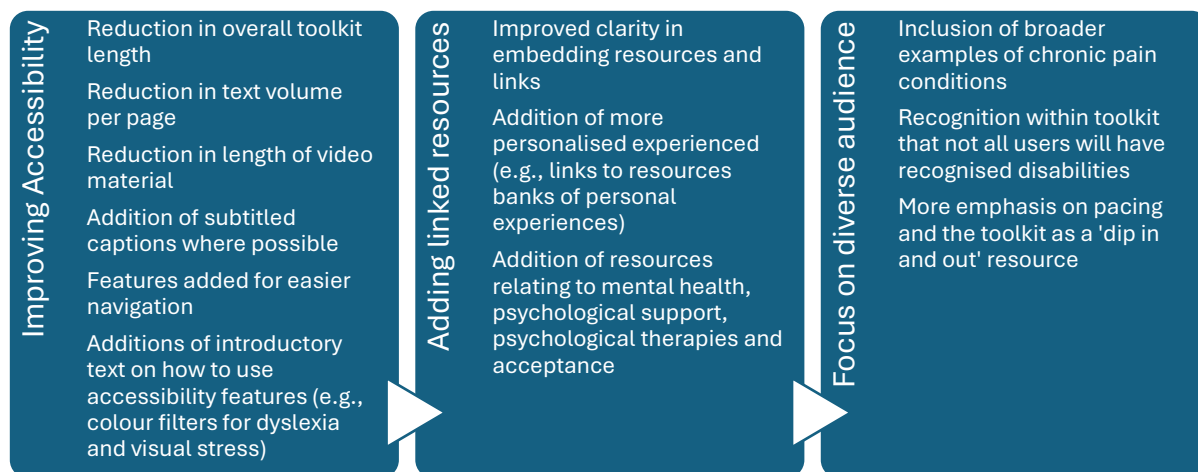
543

544 Based on these interviews, through discussion, the lead author (HB) and PPIE-partner (SG)

545 created an over-arching summary which highlighted the perceived value, to people with lived

546 experience of chronic pain, of digital interventions to facilitate the self-management of

547 chronic pain at work (Figure 5). This important view of end-users supports the rationale for

548 the PAW Toolkit and our decision to continue to with updates following its inception and co-

549 creation in 2020.

550

551 **Figure 5.** PPIE contributors' summary of key points within the interview data.

Individual and unpredictable
- Chronic pain is a very individual experience; pain and symptoms vary in different situations and over time, and flare-ups can be unpredictable.
- Chronic pain impacts on physical and emotional wellbeing.

Work impacts and mitigations
- Chronic pain impacts significantly on work, and some work situations can further exacerbate pain and fatigue.
- Reasonable adjustments can facilitate the self-management of pain, prevent or manage the impacts of pain on work, and help people to do their jobs.

Access to support
- Access to work-related support varies across employment settings.
- The level of support provided depends on employees disclosing their condition, and having supportive and understanding managers.

Self-care
- Self-care is viewed to be an important part of managing chronic pain at work.
- Digital platforms can be a useful approach to supporting people to self-manage their chronic pain and associated symptoms, and help people to better manage pain at work.

552

553

554 The specific changes made to the toolkit following survey and interview evaluation with

555 public contributors in Phase 2 are shown in Figure 6. The toolkit revisions were made

556 collaboratively by our PPIE-partner (SG) and the lead author (HB), and the final version was

557 reviewed by a second PPIE-partner (VAF). This process demonstrates not only how PPIE

558 shaped the continued development and update of the intervention (e.g., providing views and

559 guidance), but also how PPIE was embedded within the toolkit production processes (e.g.,

560 co-creation).

561

562 **Figure 6.** PPIE changes to the toolkit following Phase 2 prototype evaluation

Improving Accessibility	Adding linked resources	Focus on diverse audience
Reduction in overall toolkit length Reduction in text volume per page Reduction in length of video material Addition of subtitled captions where possible Features added for easier navigation Additions of introductory text on how to use accessibility features (e.g., colour filters for dyslexia and visual stress)	Improved clarity in embedding resources and links Addition of more personalised experienced (e.g., links to resources banks of personal experiences) Addition of resources relating to mental health, psychological support, psychological therapies and acceptance	Inclusion of broader examples of chronic pain conditions Recognition within toolkit that not all users will have recognised disabilities More emphasis on pacing and the toolkit as a 'dip in and out' resource

563

564

565 *Impact of PPIE on the research process*

566 Phase 1 PPIE contributions to PAW Toolkit development co-created the theory of change,

567 content and presentation of the toolkit. This generated a research 'intervention' and allowed

568 us to move towards prototype review and evaluation.

569

570 Phase 2 PPIE contributions to prototype evaluation established the currency of the toolkit,

571 and its ongoing value. PPIE contributions demonstrated the breadth of individual

572 circumstances, highlighting physical, psychological and organisational challenges faced and

573 a range of support accessed at work (or lack thereof). The toolkit was perceived to be an

574 empowering resource to support employees' wellbeing, validate their experiences, provide

575 employees with autonomy at work and provide opportunity for advocacy for a collective

576 understanding of chronic pain in the context of work. The toolkit and linked resources were

577 perceived to be accessible, informative and necessary. Toolkit users felt that the toolkit

578 helped to raise awareness of the rights and entitlements of people with chronic pain in the

579 workplace and found that the guidance and resources supported them in communications

580 with others in the workplace about their condition and support needs. They valued the

581 authenticity of resources which shared peoples lived experiences of chronic pain at work,

582 and the breadth of strategies, resources and ideas to support their self-management. This

583 evaluation, with minor recommendations for improvements, allowed us to move forwards to

584   review and update of the toolkit following the COVID-19 pandemic, ready for testing in a

585   feasibility trial.

586

587   Phase 3 PPIE contributions to review and update of the PAW Toolkit confirmed the validity of

588   the original theory of change, confirmed that the sections within the toolkit still aligned with

589   the priorities of people with chronic pain over time, and led to a minor update of content and

590   technical presentation which ensured that the toolkit offered advice that was current, and

591   adhered to accessibility guidelines. This allowed us to move forwards to testing the feasibility

592   and acceptability of the toolkit in a feasibility workplace trial.

593

594   Phase 4 PPIE partnerships and contributions guided our approaches at every stage of the

595   feasibility trial. We talked to members of the public about our study plans and what would

596   work well, or less well, in their view. We received suggestions about how to recruit

597   organisations to the trial, and how to motivate employees to take part in the research and

598   engage with the toolkit. Our trial PPIE-partner (VAF) has been particularly helpful in

599   supporting us to reach members of the public with our study information. All our project

600   materials were reviewed by our PPIE-partner (VAF), PPIE-members (SG + others) and

601   PPIE-contributors (n=10) to ensure that the language was accessible, and that the

602   information was relevant. This contribution improved the clarity of all our participant-facing

603   materials, including participant and employer information sheets, posters, emails, written and

604   audio-visual website information. PPIE contributions informed the design of our surveys and

605   interview topic guides and informed best practice in approaches to delivery of our

606   intervention and data collection approaches. Embedding a PPIE-partner within our research

607   team (and having PPIE representation all advisory and steering boards) ensures that our

608   regular project meetings are firmly grounded in issues that are important and relevant to

609   people with chronic pain.

610 Our PPIE-partner co-authors our academic outputs and facilitates lay dissemination which is

611 done in partnership with all members of the research team. This allows us to have

612 confidence that our trial is high quality and is relevant to our target audience.

613

614 **Discussion and conclusions**

615 In this section, we discuss components for successful PPIE, and map Pain-at-Work PPIE

616 conducted over five years to recommended components. We describe specific PPIE

617 challenges arising within our work and management strategies we adopted.

618

619 *Components for successful PPIE*

620 In response to concerns about the limitations of checklists and the need for mindful reporting

621 [25], we have gone beyond meeting the minimum requirements of the GRIPP2-SF (simply

622 reporting on checklist items). Rather, we have described in detail, and critically reflected

623 upon, each PPIE stage in separate publications. This allowed for greater depth and mindful

624 reflexive reporting in research outputs relating to our patient and public involvement

625 processes. It has been recommended that future iterations of the GRIPP consider (a)

626 incorporating criteria about whether the checklist is completed by or with service user

627 researchers or not, (b) addressing criteria that position service user research as needing to

628 be justified, and (c) expanding the "critical perspective" element of the checklist to explicitly

629 consider power differentials [25]. We have considered and reported on all three factors here.

630 Regarding (a), we completed the checklist in collaboration with our PPIE-partners from

631 various stages of this work (Phase 1-3: SG, Phase 1-4: VAF) who are both co-authors on

632 this paper. Regarding (b), our reporting relates to extensive public involvement work

633 involving several hundred individuals as public contributors (e.g., employees with chronic

634 pain, employers, healthcare professionals and other stakeholders) undertaken in direct

635 collaboration with our PPIE-partners - therefore we believe this is not confined to justifying

636 the engagement of a PPIE-partner, but rather ensuring that we have appropriately reported

637   on *how* and *when* we have engaged with members of the public and other stakeholders, and

638   the *impacts* of that, in order to inform future research.

639

640   Our key reflection is that the single most important factor of the PPIE process is that

641   researchers should deeply and fundamentally value PPIE input. Members of the public

642   should be involved in all aspects of the research from inception to dissemination and this

643   was achieved in Pain-at-Work. We found that building relationships with PPIE-partners and

644   PPIE-members and establishing networks of PPIE-contributors over time helped to ensure

645   that members of the public felt confident to share their views in workshops and meetings. In

646   our view, PPIE contributions to Pain-at-Work led to better decision-making, better-quality

647   research, and ensured that the PAW Toolkit is appropriate and relevant to the audience it is

648   designed for. We actively encourage our PPIE-partner to share their experiences of

649   contributing to this research programme with others (e.g., by contributing to PPIE papers,

650   and giving presentations at PPIE events).

651   We ensured that PPIE input was appropriately costed in our research. This was essential to

652   ensure that we could work with PPIE contributors in a meaningful way, and value their time

653   as we would any team member. It is challenging to calculate a total 'cost' for the PPIE input

654   in this complex programme of work. This is largely due to the scale and duration of the

655   development processes which took place over many years, with differing levels of funding

656   availability. At all times, large numbers of public contributors have volunteered their time at

657   various points due to a vested interest in the subject area with no expectation of financial

658   reimbursement (stakeholders, such as employer representatives, trade union and human

659   resource specialists, healthcare professionals etc). However, throughout the process, PPIE-

660   partners and contributors with lived experience of chronic pain have been reimbursed for

661   their time and input using 'payment guidance for researchers and professionals involving

662   people in research' provided by the UK National Institute for Health and Care Excellence

663   [26].

664

665 Our approach to PPIE is evidence-based, aligning with Pearson and colleagues' [27]

666 proposed 'essential components of successful PPIE' as shown in Figure 7.

667

668 **Figure 7**. Mapping of Pain-at-Work PPIE to recommended components

Employing an adaptive approach to meet individual member needs	Building a trusting and respectful partnership	Creating shared ownership and investment in the research
• using different approaches to seek public contributors' views (verbal, written, individual, group-based, face-to-face or online) • multiple PPIE stages, which provided diverse routes and platforms through which individuals might contribute • flexibility in PPIE approaches during challenging times (e.g., a pandemic requiring social distancing)	• building relationships over a 4-year period with PPIE-partners and PPIE-members • establishing broader networks with stakeholders (professional bodies, charities and individual PPIE-contributors) • advocating team meetings and stakeholder consultations as psychologically safe spaces to contribute • jointly completing GRIPP2-SF checklist with our PPIE-partners	• co-creating the toolkit content and technical presentation • involving members of the public in reviewing and updating content over time • appointing PPIE-members to oversight and advisory boards for our feasibility trial • appointing PPIE-partner(s) to study management groups as equal members of the research team • All public contributors are acknowledge for their input • PPIE-partner(s) are co-authors on research publications

669

670 Ensuring there was adequate support for PPIE-partners, PPIE-members and PPIE-

671 contributors was an important component for success. For example, we included a budget

672 for PPIE within our project grants based on INVOLVE guidance, which supported the time of

673 PPIE-partners and PPIE-members for their input (such as meeting or training attendance,

674 review of materials, support with events, collating and summarising views of broader public

675 contributor groups). We had funds to offer vouchers by way of thanks for public contributors

676 involved in various PPIE phases (such as stakeholder consultation, concept mapping

677 exercise, toolkit reviewing). In terms of mentorship, our PPIE-partners and PPIE-members

678 have been supported directly by the academic project lead (HB), and two project

679 researchers (EW, WJC). These team members facilitated the involvement of people with

680 experience of chronic pain in our trial and were the first point of contact for PPIE contributors

681 for clarification of processes or to discuss any project-related concerns. We have worked

682 directly with two national Versus Arthritis funded pain centres, that have PPIE as a core

683 component of their infrastructure. Our PPIE-partner in the feasibility trial is Founder and

684   Chair of Trustees for Burning Nights CRPS Support (a UK-based pain charity), and Chair of

685   the Expert Patient and Carer Committee at the British Pain Society – she has significant

686   experience of PPIE in research. Public contributors identified through this charity were able

687   to access support from our PPIE-partner through peer-to-peer mentoring.

688

689   *Challenges and mitigations*

690   A key strength of our study was to consider not only the benefits of PPIE but also the

691   challenges experienced. This is important since few studies report on the more challenging

692   impacts of PPIE, which could represent a publication bias [2]. Challenges were

693   predominantly experienced during group activities occurring at the toolkit development

694   stage. We mapped our PPIE challenges to themes identified in a published systematic

695   review of PPIE activity in health and social care research [2] (Table 4).

696

697   **Table 4.** Summary of PPIE challenges and management strategies

Stage of the research cycle	Challenge	Management strategy
All stages		
PPIE-partner, PPIE-member and PPIE-contributor recruitment	Difficulty in recruiting a diverse PPIE group. Initial over-representation of individuals with certain characteristics and difficulty reaching seldom heard groups (e.g., relating to gender, job role, organisation type and size, sector). Challenges related to accessibility for PPIE-contributors who had disabilities, or where English was not their first language.	Reached out to potential members via multiple routes including PPIE groups associated with the Versus Arthritis centres, and existing PPIE networks engaged with similar research. Had a high level of support from PPIE-partners for reaching other sectors. Offered recognition and reward (e.g., learning opportunities, formal acknowledgements, financial reimbursement). Budgeted appropriately for PPIE contribution. Ensured accessibility was considered in buildings where face-to-face events took place. Included remote approaches to PPIE

		contribution (i.e., online meetings, telephone, text) to include those with physical barriers to travel or keyboard use. Translation available where required.
Obtaining PPIE feedback	Some PPIE-members and PPIE-contributors did not contribute any suggestions or changes. Some PPIE-members and PPIE-contributors found it difficult to share their views in online group meetings. Some PPIE-contributors had accessibility issues for face-to-face or online meetings.	Ensured anyone involved in PPIE (partners, members, contributors) know their involvement is valued so they feel confident to contribute. Included PPIE as a standard agenda item in all meetings which was reserved 'airtime' for PPIE contributors. Provided multiple routes for individual feedback (such as online meetings, texts, emails and one-to-one in-person or telephone conversations) to engage those who may be less confident in group situations or have accessibility issues. Provided feedback on how PPIE contributions were used.
Relationship with PPIE contributors	Potential for power differentials to affect the communication of genuine views.	Encouraged individuals (PPIE partners, members, contributors) to challenge the status quo. Maximised long-standing relationship with our PPIE-partners who acted as a conduit to reach people with chronic pain and other stakeholders. Multiple routes for feedback which allow avoidance of communicating contrasting views publicly. Contrasting views presented back to the PPIE contributors for consensus building. Provided details of future PPIE opportunities.

Resources: Time	Time burden for the research team associated with engaging PPIE (partners, members, contributors) in planning and conducting research.	Additional time built into the study schedule, and all team members briefed on the importance of PPIE to be able to move to the next research stage.
Resources: Cost	Financial implications of PPIE at every stage of the research cycle.	Appropriately costed for PPIE input using INVOLVE guidance. Targeted research funders that actively encouraged PPIE engagement and supported PPIE budget.
Intervention design and development		
Design of the PAW Toolkit – stakeholder consultation event group activities	Difficulty in maintaining PPIE-contributor confidentiality within meetings, where attendees discussed personal experiences.	Maintained a dialogue about confidentiality and professionalism.
Design of the PAW Toolkit – stakeholder consultation event group activities	Groups being dominated by strong characters and their perspectives, leading to over-emphasis on particular issues.	Engaged in careful and inclusive facilitation practices to allow a fair representation of voices and allow conversations to cover diverse issues
Design of the PAW Toolkit – stakeholder consultation event group activities	Groups being overshadowed by personal experience stories, when the aim was to identify and agree on PAW Toolkit content and presentation.	Provided clear instructions for the meeting. Engaged in careful facilitation practices, bringing conversations back to topic.
Design of the PAW Toolkit – stakeholder consultation event group activities	Groups being seen as a forum for those with lived experience of pain to access personal health advice from healthcare professionals in attendance (groups included researchers, clinicians, employment specialists, policy makers).	Communicated clear expectations for the session outlined and careful facilitation practices, bringing conversations back to topic.
Design of the PAW Toolkit – stakeholder consultation event group activities and expert peer review of content and presentation.	PPIE-contributors shared information about the PAW Toolkit content externally prior to completion of the co-creation activity and end of the development phase.	Communicated clear expectations for PPIE involvement and open dialogue about research integrity. Training offered for PPIE partners, members and contributors.
Time-lag between PAW Toolkit design and feasibility testing	A long-lasting global pandemic led to a time-lag between development and feasibility	Conducted a concept mapping study with a

	testing which then required additional PPIE work to update and refine the toolkit content. Most original PPIE-contributors were not available.	new PPIE-contributor group. Long-term relationship with PPIE-partners helped to sustain the connection between the original co-creation activities, PPIE required for the toolkit update and PPIE in the feasibility trial.
Feasibility cluster randomised controlled trial		
Design of feasibility trial baseline and follow-up surveys	Difficulty in balancing traditional academic criteria for high-quality research, such as the use of standardised research measures, and PPIE (partner, member, contributor) perspectives.	Reduced unnecessary jargon and text in data collection tools. Reached out to a broader PPIE-contributor group and took the majority view. Compromises were reached to ensure PPIE member views were incorporated in alignment with the research aims.
Membership of Trial Management Group	Potential for lack of clarity regarding whether PPIE-partners are 'part of' the research team, or 'supporting' the research team.	Assigned a named PPIE-partner to the Trial Management Group, who is considered an equal contributor to the research team and acts as co-author on publications. PPIE-members are external to the trial management–they hold advisory positions through structured groups (Trial Advisory Group, Trial Steering Group) or direct approach as needed (PPIE-contributor groups or individuals)
Dissemination and communication of trial findings	Concerns that PPIE-partners, PPIE-members or PPIE-contributors may disseminate the study results before they have been written up and published in academic journals, thus jeopardising scientific publication.	Maintain open dialogue and communication relating to confidentiality of study findings prior to publication.

698

699 **Reflections and critical perspective**

700   In this section, we reflect on the evolving guidance, policies and resources available to

701   researchers around PPIE. We consider some of the key challenges to PPIE (outlined in

702   Table 4) in more depth, and the value of our PPIE beyond the current research programme.

703   We consider the limitations of our PPIE approach. Finally, we provide a summary of a

704   learning with recommendations based on our own experiences that could be considered by

705   other researchers.

706

707   *Policies and guidance*

708   In the UK, there are numerous policies, strategies and standards providing guidance on

709   PPIE, often with a focus on collaboration and communication, inclusive opportunities, ethical

710   considerations, governance and impact, safeguarding and confidentiality, and building

711   sustainable relationships. PPIE is, arguably, more established in health and social care

712   compared to other fields. This is largely due to: (a) legal and ethical frameworks (health and

713   social care organisations often have statutory duties to involve the public in decision-making)

714   [28], (b) historical development of PPI through early emphasis on patient safety and service

715   improvement) [29], (c) funding support (many health research funders require PPIE as a

716   condition of funding) [30]. For example, The National Institute for Health and Care

717   Excellence has published a 'Patient and public involvement policy' to guide the involvement

718   of lay people, and organisations representing their interests in contributing to developing

719   NICE guidance, advice and quality standards, and supporting their implementation [31].

720   NHS England has published a 'Patient and Public Participation Policy' [32] relevant to the

721   involvement of patients, the public, and NHS staff. The UK Standards for Public Involvement

722   [33] are designed to improve the quality and consistency of public involvement in research.

723   They were produced by the UK Public Involvement Standards Development Partnership

724   which brings together representatives from the Chief Scientist Office (Scotland), Health and

725   Care Research Wales, the Public Health Agency (Northern Ireland) and the National Institute

726   for Health and Care Research (England) working with an independent expert. The

727   partnership showcases experiences from 10 different 'test bed' projects which have applied

728   the UK Standards in a range of contexts [33]. Health Data Research UK shares guidance on

729   'Involving and engaging patients and the public', including principles for how to achieve the

730   UK Standards for Public Involvement [33, 34]. The National Institute for Health and Care

731   Research have produced briefing notes for researchers on public involvement in the NHS,

732   health and social care research [35] and The NHS Health Research Authority has published

733   best practice on public involvement in health and care research [36].

734   PPIE is rapidly involving in other sectors. The UK Research and Innovation (UKRI) is the

735   UK's national funding agency for research and innovation, supporting research across

736   various disciplines, including science, technology, social sciences, and the arts. It is

737   composed of seven research councils, Innovate UK, and Research England. UKRI has an

738   overarching public engagement strategy [37] which aims to break down barriers between

739   research, innovation and society, through a sense of shared endeavour, supporting

740   collaboration and opportunities and valuing diverse knowledge.

741

742   *Reaching under-served groups*

743   Although we had initial challenges in reaching under-served groups, our successful

744   strategies (Table 4) involved working with professional networks and groups, including

745   recognition and reward, appropriate budgeting, addressing accessibility issues and being

746   flexible in our approaches. It is widely accepted that under-served groups are under-

747   represented in research and PPIE [38, 39]. In the UK, considerable efforts have been made

748   to provide detailed guidance on which groups are considered under-served, and how to

749   improve representation of these groups in research [39, 40]. In the NIHR INCLUDE project,

750   Witham and colleagues [40] proposed four key goals to achieving this: building long-term

751   relationships with under-served groups, developing training resources to improve design and

752   delivery of trials for under-served groups, developing infrastructure and systems to support

753   this work and working with funders, regulators and other stakeholders to remove barriers to

754   inclusion. Our development processes reached a diverse group of public contributors

755   overall. We had a diverse group of public contributions in the Phase 1 stakeholder

756   consultation, employer and employee surveys, and expert peer review. In Phase 2 we had a

757   diverse group completing the public and professional evaluation surveys. However, we did

758   not achieve diversity in our 15 Phase 2 interviews. This may have been impacted by our

759   contributors being sourced by, and interviews being conducted by, a White British PPIE-

760   partner. Future support for PPIE-partners engaging in seeking the view of public contributors

761   in the context of workplace-based research could include (a) more training in ways to

762   actively engage with underrepresented employee groups through targeted outreach and

763   partnerships, (b) having more diverse teams (the researchers and PPIE-partners engaged in

764   seeking public views), and (c) working more closely with employee network groups, such as

765   Black and Minority Ethnic Staff Networks.

766   A wealth of toolkits is now available to support researchers in increasing the participation of

767   under-served groups in research and PPIE. For example, the NIHR Applied Research

768   Collaboration for the East Midlands provides a toolkit for "Increasing Participation of Black

769   Asian and Minority Ethnic Groups in Health and Social Care Research" [41], the COMET

770   Patient and Public Involvement Toolkit includes strategies for engaging diverse groups in

771   core outcome set studies [42], and the NIHR INCLUDE Project [39] offers a roadmap for

772   improving inclusion of under-served groups in clinical research, with examples of barriers

773   and strategies to overcome them. Our experiences, and these toolkits highlight the

774   importance of building trust through community partnerships (e.g., with local organisations,

775   faith-based groups, and trusted community leaders), having cultural humility and using

776   culturally sensitive approaches, expanding communication channels to widen accessibility,

777   and addressing systematic barriers (e.g., transportation issues, digital access limitations,

778   and consultation fatigue).

779

780   *Adapting to unanticipated events*

781   The COVID-19 pandemic occurred in-between developing the toolkit and evaluating it which

782   meant that all our face-to-face PPIE activity moved online due to pandemic-related social

783   restrictions. This was followed by longer-term changes in ways of working for researchers,

784 PPIE-partners, PPIE-members and PPIE-contributors (i.e., hybrid and remote working) and

785 so we retained our online approach. We thought that the lack of face-to-face contact might

786 be challenging, but it worked very well and in fact, made our meetings more accessible to

787 individuals with competing demands on their time, disabilities or barriers to travel. While

788 remote work has challenges, we had management strategies to overcome this (see Table 4).

789 There are key benefits of this approach in terms of lower costs, lower impacts on people's

790 time, greater flexibility, and less travel for those involved in PPIE which can be important for

791 those living with chronic pain and means that our study has a low environmental impact.

792

793 *Maintaining confidentiality*

794 One of our greatest challenges was preventing PPIE contributors from disclosing

795 confidential research plans or findings externally, thus jeopardising scientific publication and

796 our dissemination plans. This required a proactive strategy, involving clear communication at

797 the outset, to set expectations for all involved and explain what information is confidential

798 and why it must be protected. Our activities were GDPR compliant, we shared only

799 information that was relevant and necessary at each phase, and restricted access to

800 sensitive data. PPIE training and support included ethical research practices and the

801 importance of confidentiality. We followed NIHR ethical practice guidelines for public

802 involvement (e.g., [43]). Finally, for those members of the public who contributed to more

803 than one phase, we reinforced confidentiality obligations through periodic reminders and

804 discussions.

805

806 *Recognising and minimising the impact of power differentials*

807 Power differentials in PPIE refer to the imbalances in influence, authority, and decision-

808 making between researchers, stakeholders (such as healthcare professionals) and members

809 of the public involved in research or policymaking. These disparities can affect the extent to

810 which members of the public feel able to engage and contribute, and ultimately the influence

811 they have in shaping research. Findings ways to address power balances has been

812   identified as an important aspect of making public involvement work [44]. A key aspect of

813   managing power imbalances is to ensure that the perspectives of those with lived

814   experience or formal expertise are valued equally. In our PPIE, this was achieved in several

815   ways. First, through our co-production approach to toolkit development and testing (through

816   inception, content building, technical presentation, and evaluation) and second, by the

817   appointment of PPIE-partners as equal members of the research team. We adopted less

818   hierarchical structures by including members of the public as equal members of advisory

819   and steering boards (PPIE-members) and held events at which diverse stakeholders – such

820   as people with lived experience, employers, and healthcare professionals - engaged in 'view

821   sharing' or 'decision-making' activities together as equals. While retaining flexibility for

822   individuals to choose to contribute in other ways that avoid communicating in public settings.

823   We sustained relationships with PPIE-partners, built our networks of employer

824   representatives and healthcare professionals over many years, and consistently respected

825   their views. Building equitable partnerships has been identified as an important approach to

826   reducing power imbalances in co-production [45].

827

828   *Strengths and limitations of our approach*

829   Our PPIE is perceived to be comprehensive by our PPIE-partners and contributors, and we

830   aimed to be as inclusive as possible in our approaches, genuinely integrating public

831   perspectives and addressing any known barriers to engagement. Co-production and public

832   consultation are the 'norm' in our team's research practices. This is a strength, given

833   concerns about 'tokenistic' PPIE practices, whereby PPIE may be conducted superficially as

834   a 'tick-box' exercise, or only for reasons of compliance with funder requirements [46].

835   Despite our efforts to be inclusive, there may be individuals who did not engage in our PPIE

836   for reasons unknown to the research team – this could be a lack of awareness or

837   understanding, study timing, accessibility issues (such as language, culture, disability, or

838   digital exclusion), resource constraints, perceived power imbalances or perceptions of the

839   academic 'context' (e.g., as intimidating or complex) [29]. Except for the 'numbers of

840   contributors' involved at each stage, we have not presented quantifiable measurements for

841   PPIE such as 'number of meetings held'. However, this was a conscious decision as we

842   preferred to focus on the breadth and quality of engagement and its influence on research

843   decisions, processes and outcomes.

844

845   *Going forwards*

846   Our summary of the learning from our PPIE, and recommendations for other researchers

847   can be found in Table 5. The PPIE input in this programme of research goes beyond the

848   immediate project and helped us to determine the key advantages and challenges of web-

849   based interventions for training and health behaviour change. For example, feedback from

850   PPIE-partners and contributors in our Phase 4 feasibility trial, combined with learnings from

851   other web-based workforce studies, informed the development of the "Web-based Workforce

852   Health Intervention Development and Evaluation Framework" (WWHIDE Framework: [47])

853   [Additional file 6]. WWHIDE was developed by the lead author and colleagues and is the first

854   framework to present key considerations around the recruitment of employers and

855   employees, intervention design and development, delivery modality, comparison groups for

856   trials, intervention engagement, attrition rates, and user acceptance. Insights from our PPIE-

857   partners and contributors have therefore reached beyond direct input to the trial and have

858   relevance to the design of future health research studies involving web-based interventions

859   for education, training, and behaviour change.

860   A study exploring the implementation of PPIE across Europe found that PPIE was "not firmly

861   embedded or adequately formalised in European healthcare systems and research" [48].

862   Given the widely accepted vision that PPIE should be embedded in all health research, we

863   contribute to PPIE practice and the evidence-base in this field. Our worked example of PPIE

864   may serve as a catalyst for other researchers to consider planning, documenting and

865   critically appraising PPIE throughout the research cycle.

866

867   While the PAW Toolkit is focused on a health topic (chronic pain), it's development,

868   evaluating and testing has taken place outside of health and social care (workplaces), albeit

869   involving healthcare professionals as 'stakeholders' in expert review and evaluation of

870   content. The application of PPIE in organisational research outside of health and social care

871   is less commonly discussed – and is rarely covered in depth. Our extensive PPIE activity is

872   highly relevant to health and social care researchers and our approaches to PPIE in digital

873   intervention development have broad applicability across health areas. However, the breadth

874   and depth of our work is particularly novel in the context of workplace research, albeit this is

875   an emerging area. Here, we have presented the benefits, challenges and approaches to

876   'best practice' in PPIE in the development and evaluation of an intervention conducted in the

877   workplace settings. Our learning points and recommendations are transferable to other

878   national and international health research contexts and settings.

879

880 **Table 5**. Summary of learning points and recommendations.

881

Learning points		
Advantages of PPIE to the Pain-at-Work research	Descriptions	Selected examples
Improved relevance of the toolkit	Our research is better aligned with the needs and priorities of people with chronic pain, making findings more impactful.	Phases 1-3: We co-created the concept, content and technical presentation of the PAW Toolkit and engaged expert peer reviewers throughout the development and update processes (including people with lived experience). Our PPIE processes ensured we were addressing real-world concerns and priorities. Phase 2: Our evaluation confirmed that the toolkit was usable, relevant and appropriate for people living with chronic pain.
Better study design	Public input helped ensure that our studies were designed in a way that is acceptable and understandable to participants	Phase 4: Our PPIE-partners helped to select the outcome measures that were used in our feasibility trial – these reflected the outcomes that were most important to people living with chronic pain.
Enhanced ethical considerations	We were able to identify possible ethical concerns early and come up with solutions.	Phase 4: Our feasibility trial was designed so that individual employees did not have to disclose their health conditions or their participation in the feasibility trial to their employer. No health data was shared with employers by the research team. The digital intervention (PAW Toolkit) and study materials adhered to accessibility guidelines.
Better recruitment and retention	We were able to find the best routes to reaching organisations of different types, sizes and sectors.	Phase 4: PPIE improved our outreach to organisations and employees for recruitment, by suggesting specific professional networks and organisations to approach. We acted on suggestions for reaching a diverse research sample in our feasibility trial, such as working with Trusted community leaders and engaging with staff networks (e.g., Black and Minority Ethnic Staff, Disabled Staff). We enhanced accessibility (of information and the research team) by simplifying information sheets and website materials and providing

	We identified the most appropriate routes to recruiting and retaining employees in a trial.	alternative forms of communication. Text messaging reminders and an opt-in prize draw incentive were proposed to maximise retention. The evidence of success is that we exceeded recruitment targets. The feasibility trial included 18 organisations (50% over target) and 380 employees (217% over-target). Both our recruitment and retention rates demonstrate feasibility of the trial processes.
Clearer communication	PPIE ensured that our participant information for research participants was understandable, improving informed consent and engagement. Findings were more effectively shared with participants and the wider public, improving transparency	Phase 1-4: People with lived experience contributed to our website information, study promotional materials, participation information sheets and consent forms, lay summaries of findings, PPIE 'case studies' of best practice, and research outputs. Our PPIE-partners were involved in written and oral dissemination.
Higher-quality research	Involving the public led to a better-designed and conducted study, and more meaningful research.	Post Phases 1-4: The research team and PPIE-partners critically reflected on the process and outcomes using the GRIPP2-SF. The PPIE is reported here with detail and transparency.
Recommendations for researchers embarking on PPIE		
Involve the Right People	Engage individuals with relevant lived experience to ensure the research is meaningful and impactful. Involve other key stakeholders with a vested interest in the subject area, service delivery, commissioning or supporting those with lived experience.	
Early and Continuous Engagement	Involve the public from conception and design stage through to dissemination to improve study relevance and explore ethical considerations. Build relationships and networks with the public over time.	
Clear Communication	Clearly outline expectations, including time commitment, project duration, and the value of PPIE input. Make research findings accessible and understandable to participants and the wider public.	
Two-Way Interaction	Public involvement should be more than just informing; it should allow for feedback and collaboration.	
Flexible approaches	Use a range of methods such as individual or group discussion, peer review panels, interactive workshops, surveys, videocall and email communications.	
Ethical considerations	Ensure ethical approval is obtained when necessary and differentiate between research and PPIE activities.	

Adequate Support and Resources	Provide training and resources for public contributors to ensure their involvement is effective and valued.
Reflection and transparency	Use a framework to document and evaluate PPIE activity. Be transparent about the processes and decision-making. Evaluate how PPI has influenced research design, methodology, data analysis, and dissemination. Assess whether PPIE has led to more person-centred research, improved accessibility, and greater public engagement over time. Reflect on the benefits and challenges together with PPIE contributors. Share learning with other researchers and the public.

882
883

884 **List of Abbreviations**

885 **GRIPP** Guidance for Reporting Involvement of Patients and the Public

886 **GRIPP2-SF** Guidance for Reporting Involvement of Patients and the Public 2 Short Form

887 **PAW** Pain-at-Work

888 **PPIE** Patient and Public Involvement and Engagement

889 **SME** Small-to-medium sized enterprise

890 **WWHIDE** Web-based Workforce Health Intervention Development and Evaluation

891

892 **Declarations**

893

894 **Ethics approval and consent to participate**

895 As UK-based PPIE and intervention development activity, ethical approval was not required

896 and since PPIE contributors are not research participants they are not required to give

897 formal written consent for their involvement. The PPIE activities in the creation and

898 evaluation of the PAW Toolkit (Phases 1-3) did not require research ethics approval as they

899 were classified as public consultation and educational development by the University of

900 Nottingham Faculty of Medicine and Health Sciences Research Ethics Committee (Ref:

901 FMHS 358-0921; 08 Jan 2020 and 27 September 2021). The same committee subsequently

902 granted research ethics approval for the PAW Toolkit feasibility trial (Ref: FMHS 237-0323;

903 31 March 2023) – although ethical approval is not required for PPIE activity, this trial

904 approval does include our Phase 4 PPIE plans.

905 As good practice, across Phases 1-4, our PPIE-partner and public contributors were made

906 aware of the nature of their involvement, their right to withdraw when they wish, any

907 implications and risks of being involved. For synchronous PPIE activity, including the Phase

908 1 stakeholder consultation event and the Phase 3 concept mapping exercise, two

909 researchers (HB, SS) documented 'informed verbal consent' for synchronous activity in the

910 presence of the group. For asynchronous PPIE activity 'informed assumed consent' was

911 taken, including Phase 1 anonymous online PPIE surveys with public contributors

912 (employees/employers) and expert peer review (public contributors/stakeholders), Phase 2

913 expert peer review, and anonymous PPIE evaluation feedback surveys with PAW Toolkit

914 users, and Phase 3 expert peer review. For Phase 2, our PPIE-partner (SG) gathered

915 'informed written consent' from public contributors sharing their views in interviews. In Phase

916 4, while our PPIE-partner provided verbal consent, written consent is not required as she is

917 considered an equal member of the research team.

918

919 **Consent for publication**

920 Not applicable.

921

922 **Availability of data and materials**

923 The datasets generated and analysed during the current study are not publicly available to

924 protect the privacy of PPIE contributors. Data may be available from the corresponding

925 author upon reasonable request.

926

927 **Competing interests**

928 Authors HB, VAF, SG, and SS are authors of the Pain-at-Work Toolkit. The authors declare

929 no other competing interests.

930

937

938 **Authors' contributions**

HB conceived of the study, designed and oversaw all phases of PPIE, wrote the manuscript text and prepared all figures, tables and additional files. HB, VAF, SG and SS developed and authored the Pain-at-Work Toolkit (Phase 1). HB and SS hosted the stakeholder consultation, SG and WJC facilitated discussion (Phase 1). HB, VAF, SG and SS conducted the online surveys. HB, SG SS coordinated expert peer review with input from VAF (Phase 1). HB and SG coordinated expert peer review, qualitative and quantitative prototype evaluation, with input from VAF (Phase 2). HB and VAF conducted the concept mapping exercise and coordinated expert peer review for toolkit update (Phase 3). HB, WJC, EW and KWB designed and coordinated PPIE for the feasibility cluster randomised trial (Phase 4). All authors reviewed and approved the manuscript.

970

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1149   **Supporting information captions**

1150   **Additional file 1:** GRIPP2 short form

1151   **Additional file 2.** PAW Toolkit PPIE Evaluation Survey

1152   **Additional file 3.** Characteristics of Phase 2 public contributors (n=104)

1153   **Additional file 4:** Challenges and routes to support

1154   **Additional file 5:** Public contributors' views towards the PAW Toolkit

1155   **Additional file 6:** WWHIDE Framework