Plan Overview

A Data Management Plan created using DMPonline

Title: The Pain-at-Work Toolkit or employees with chronic pain (definitive trial)

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Template: University of Nottingham Staff/PGR Data Management Plan

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Project abstract:

Chronic pain affects 28 million adults in the UK, with a projected increase of 32% by 2040. It accounts for societal costs equivalent to 4% of GDP, with 80% of these costs linked to work productivity loss. People living with chronic pain often face barriers to productivity and workforce participation, exacerbating social inequalities such as the disability pay gap. Existing support services and workplace interventions rarely address work-related outcomes for individuals with chronic pain, particularly those with multiple conditions or those who are not accessing healthcare services.

The Pain-at-Work Toolkit offers a scalable, evidence-based solution to address unmet needs, improving work ability and reducing social inequalities. The project builds on previous research, which demonstrated the feasibility and acceptability of the toolkit.

This study is an open-label, two-arm, cluster-randomised controlled trial (cRCT) comparing the Pain-at-Work Toolkit with a Support-as-usual (standard employer support) control group among working adults with chronic pain. The analysis will be performed on an intention-to-treat basis. The study setting is UK employment settings (referred to as ‘organisations’) in different sectors (public, private, third), varying in size (small:10-49 workers; medium: 50-249 workers; large: >250 workers).

We will work with around 70 organisations from different types of workplaces in the UK and invite more than 685 employees who live with pain to take part in the study. Organisation's employees will either receive access to the Pain-at-Work Toolkit and the Pain-at-Work Managers Toolkit (to help managers support their staff) or the standard care that their organisation offers. Participants will be asked to complete online surveys at three points during the study. Intervention participants may be asked to take part in an interview at the end of the study to find out more about their experiences.

The study will examine whether the toolkit helps improve people’s experience of work, including their productivity and ability to stay productive in their jobs. We will also explore whether the toolkit offers good value for money.

Finally, we will examine how the toolkit is used in practice—what works well, what might need improving, and how it could be made available to more employees in the future. We will do

this by interviewing employers or stakeholders involved in the employment of, support for, or policy development for adults with chronic pain.

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The Pain-at-Work Toolkit or employees with chronic pain (definitive trial)

Data description

What data will you create?

Both qualitative and quantitative data will be collected.

Quantitative data is collected at 3 time -points: baseline, 3 months, 6 months.

Employer sickness absence records (electronic).

Employer survey: Sector, type, and size, Number of staff, Support as Usual (SAU) – existing provisions to support staff with long-term health conditions, Roles of employer representatives will be recorded as part of the trial, (e.g., CEO, Human Resource Manager, Line Manager, Occupational Health or other) together with their views towards the organisation's culture.

Employee survey: socio-demographic (age, gender, ethnicity, income, education), health (pain condition(s), comorbidities, medications), employment characteristics (job role/type; sector; size/type of employing organisation; job tasks) and assessment of participants perception of organisation culture, policy and practices to support people with health conditions to remain working). Service access. Participant reported outcomes measures, including Work-related measures; Psychological and Health-related Quality of Life measures; Health resources use, Technology-adoption.

Interviews with employees, employers or stakeholders involved in the employment of, support for, or policy development for adults with chronic pain

Questionnaire results will be downloaded from SmartSurvey online survey onto excel document (*.xlsx). Audio-recordings will be made using Microsoft Teams and saved as audio/visual MP4 files (.mp4). Some may be recorded using a free voice recorder App, saved as .wav files to prevent compression of sound quality.

Interviews with some participants saved as audio/visual MP4 files (.mp4). These will be saved to the Microsoft Stream with the appropriate privacy settings ensuring that only the project team can access the recordings. Interviews will be transcribed into Word documents (.docx) researcher notes and observations will be recorded in Word (.docx) Files will be uploaded into NVivo for further analysis. (audio file, transcribed into word document *.docx)

Participants will complete questionnaires electronically if able, with a paper copy as backup. Hard copies of data and electronic data will be input into an Excel spreadsheet (.xls). Data will be saved on UoN OneDrive. Excel files will be uploaded into STATA for analysis. Stata files (.dta) will be downloaded and saved alongside other research data on UoN OneDrive.

Data collection / generation

What are your methodologies for data collection / generation? How will you ensure data quality?

Data will be collected as part of the cluster randomised multi-centre feasibility trial with process evaluation following a mixed methods methodology.

Pre and post-measures will be collected at baseline, 3-month, and 6-month time points. The data collected is described in the "data description" section. Some files will be created later in the analysis e.g. STATA analysis of excel data and NVivo files.

Data will be collected in writing, electronically and through audio recording. Data is required to understand the feasibility of collecting different types of data in order to consider the appropriacy of a future larger effectiveness study.

Data collection tools are piloted with our PPI group to ensure the instructions are easy to follow, that the formatting works and to time the data completion.

The consistency and quality of data collection will be supervised throughout by the study management group. Where data is collected by hand and transferred to an excel spreadsheet, data will be checked at the time of inputting by the inputter with a further 10% of the data checked prior to commencing any analysis to ensure that there are not any mistakes.

Once recruited, all participants will have a unique anonymous study number, generated by random number generation and this will be used on documentation.

Personal Data

Where any research project involves the collection, processing or storage of Personal Data, a DPIA screening must be undertaken to determine whether a Data Protection Impact Assessment (DPIA) may be required.

A Data Protection Impact Assessment will be conducted. The same data was collected in the feasibility trial.

We will collect organisational records of sickness absence rates for participating employees from their employer (for those employees who provide consent).
We will collect self-reported data from employees using questionnaires: Socio-demographic (age, ethnicity, income, education)
Health (Brief Pain Inventory-Short Form, pain condition(s), comorbidities, medications), technology (familiarity with online technology)
Employment characteristics (job role/type; sector, size/type of employing organisation /job tasks)
Questionnaire measures of: Work presenteeism, work ability, fear avoidance beliefs Questionnaire-Work
• Self-efficacy to work (e.g.,0-10 numerical self-rating scale)
• Job satisfaction (Dolbier et al, 2005)
• Job stressfulness (Houdmont et al, 2019)
• Number of days sick leave (previous 3-months).
• Turnover intentions (Ryan et al, 2017)
Psychological and Health-Related Quality of Life (HRQoL) PROMs
• Patient Health Questionnaire (PHQ-9: Kroenke et al, 2001) –depression
• General Anxiety Disorder (GAD-7: Spitzer et al, 2006) –anxiety
• EQ-5D-5L -HR-QoL
Technology-adoption PROMs (12w, intervention group only)
• Technology Acceptance Questionnaire (TAM: Davis,1989) –perceived usefulness, ease of use, enjoyment, behavioural intention.
• Items on routes to accessing PAW, time spent engaging with PAW/support,

This is time-limited - it is a research project lasting 36 months overall. Data will be collected via online surveys at three time points per participant (baseline, 3 months, 6 months). Data collection will take place over an 18-month period (due to rolling recruitment of participants).

Data will be stored in the UK and not transferred outside of the UK

The personal data: name, initials, year of birth, email , and mobile telephone number (optional),

via pseudo-anonymised user number : Job details, Salary and Performance Bonus information, ethnicity, and health.

Participants are working adults aged 18 or older employed in the UK with chronic pain interfering with their ability to undertake or enjoy productive work, able to comprehend English language and provide informed consent.

Data storage and security

Where and how will your data be stored, backed-up, transferred, and secured during the active phase (short to medium term) of research?

We will use UoN-provided storage for our working data. UoN licenses Microsoft Teams, allowing for secure and controlled sharing of data among the research team. Microsoft Teams encrypts data both in transit and at rest and is approved against the University's Handling Restricted Data Policy. The service provides several layers of automatic back up and, in a disaster scenario, files can be recovered. Access to data stored in MS Teams is via secure log-in with multi-factor authentication. We will use UoN Central

Performance Storage for our working data. This storage is designed for high-throughput data or large files. The storage is on-premise and approved against the University's Handling Restricted Data Policy. Files are automatically backed up, and files older than 24 hours can be recovered in a disaster scenario. Paper files will be stored in a locked filing cabinet. Data will be stored against participant IDs to protect individuals from being identified and ensure the data is anonymised.

Interviews may be transcribed by a University-approved transcription service. Audio and video files will be securely transferred to this service via Mailbigfile, which uses encryption and security measures, including a secure 128-bit SSL connection, and passwords. Transcripts will be anonymised with identifiable information extracted. Once transcribed the recording will be destroyed.

Each participant will be assigned a trial identity code number, allocated at randomisation if appropriate, for use on CRFs other trial documents and the electronic database.

A study recruitment log will be maintained in a separate password-protected file, containing the participant's trial identity and identifiers, along with their name and contact details, and will be accessible by the CI and the Project Researcher.

Data management, documentation, and curation

What are your principles (e.g. FAIR), systems, and major standards for data management and creation? What metadata and documentation will you keep? What file formatting and naming conventions will you adopt?

Data will be organised into separate folders and files for the different stages of research and saved onto the UoN provided storage. A main 'data' folder will be created. Within this, separate folders will be created for each data type: questionnaire responses, demographics forms, audio data, transcription data. All files will be named using an anonymised participant ID. Files will be titled with a description of the data, version number and date.

Metadata in the format of a Microsoft word or Excel document will also be used, with descriptions of the analysis performed and reference to the file names/version numbers. This will ensure that research data can be used by others outside of the project team. The researcher will document the procedures, objectives, and methodology of the research, and explicitly describe the meanings of variables and codes used. This information will be saved to a file within the main data folder. Any derivations, transformations, pseudonymisation or data cleaning will be described and saved in password protected files where relevant.

Ethics and privacy

Are there any ethical, commercial, or privacy issues that will affect the collection and storage of your data? E.g. For research involving humans, human tissue samples and animals.

All study staff will endeavour to protect the rights of the study participants to privacy and informed consent and will adhere to the Data Protection Act 1998 and GDPR (Data protection Act 2019). This will include providing research participants with the relevant privacy information and ensuring appropriate safeguards for the storage and handling of data are in place. The study will only collect the minimum required personal information for the purposes of the study. Personal data will be collected during this project, and the project has considered ethical and legal implications in its data storage, as well as appropriate security of personal data. All participants will agree to data collection and to long-term retention, archiving, and sharing of their anonymised data. Research will follow standard ethical procedures of the University of Nottingham. Participants will be informed that they can withdraw their participation at any stage of the study, although data collected will be used in the analysis.

Commercial software packages will be used throughout the project, and for all software used, the appropriate usage licences will be held.

Data preservation and archiving

How will you ensure the long-term storage and preservation of data?

All anonymised research data created by the project will be deposited in the UoN research data archive

(https://rdmc.nottingham.ac.uk). UoN will retain and preserve research data in line with UoN and Nuffield Foundation/ Arthritis UK requirements for a minimum of 7 years, but data will be retained for longer periods of time where it is of continual value to users.

Data sharing and access (internally and externally)

How will the data generated be shared and published securely? Have all the required agreements been considered?

We will ensure that our research aligns with the requirements of the University's Research Data Management Policy, Information
Security Policy, Code of Research Conduct and Research Ethics. As we are working with personal data, we will abide by the University's Handling Restricted Data Policy and Data Protection Policy. All third party commercial data or new data that may be suitable for commercial exploitation will be protected by the University's Intellectual Property policy.

Data deletion and destruction

What data must you keep and what data can be deleted/destroyed?

Interviews may be transcribed by a University-approved transcription service. Audio and video files will be securely transferred to this service via Mailbigfile, which uses encryption and security measures, including a secure 128-bit SSL connection, and passwords. Transcripts will be anonymised with identifiable information extracted. Once transcribed the recording will be destroyed.
A study recruitment log will be maintained in a separate password-protected file, containing the participant's trial identity and identifiers, along with their name and contact details, and will be accessible by the CI and the Project Researcher. Once the trial is complete this file will be destroyed fully anonymising the data.

Roles and responsibilities

Who will be responsible for managing data, data security, and data quality both during the project and once the project has finished?

The chief investigator and project researcher will be responsible for the storage and management of the data collected during this study. The overall responsibility for data security is held by the University of Nottingham Chief information security officer. Whilst the data is being analysed it will be accessible to the study team, the use of UoN One Drive will facilitate this and allow for team members based at different locations to still have access to the data set. All project members are required to follow the DMP. All project members are responsible for their own use and management of data.

Relevant policies

What are the relevant institutional, departmental or study policies on data sharing and data security?

We will ensure that our research aligns with the requirements of the University's Research Data Management Policy, Information
Security Policy, Code of Research Conduct and Research Ethics. As we are working with personal data, we will abide by the University's Handling Restricted Data Policy and Data Protection Policy. All third party commercial data or new data that may be suitable for commercial exploitation will be protected by the University's Intellectual Property policy.

Intellectual property

Who will own the copyright and IPR of any data that you will collect or create? Will you create a licence(s) for its use and reuse? If you are planning to use existing data as part of your research, do any copyright or other restrictions determine its use?

Copyright & IPR for all project research data is owned by the University of Nottingham.

Budgeting

What are the anticipated costs for managing, storing, archiving and sharing research data?

The study has been funded by the Nuffield Foundation and Arthritis UK Oliver Bird Fund held by the principle investigator, Professor Holly Blake (OBF /FR-000025871) and therefore all costs are accounted for. We do not anticipate any costs beyond those already accounted.

Governance

Completed DMPs must be uploaded into RIS, document module.
The DMP must be considered a living document and updated with the relevant details throughout the life of the project.

The completed DMP will be saved in the site file and reviewed regularly throughout the project.

Further Help

Tick the box below if you would like your DMP to be reviewed by specialists in Libraries. Please note this is not a necessary step for Ethics approval - Libraries can offer guidance on best practice around DMPs, but are not involved in the Ethics process.

Saving this plan after checking the "Yes" box will immediately notify Libraries DMP review service, please only do this when you are ready for review.

- No

Would you like a reminder and further guidance on depositing your data? If so, indicate when would be most useful.

Guidance is sent out twice a year, but you can contact library-researchsupport@nottingham.ac.uk at any time for further support.

- No further support

Tickbox Testing

Does this research project involve the collection of personal data?

- Yes

Name,
initials
year of birth
mobile number (optional)