
Plan Overview

A Data Management Plan created using DeIC DMP

Title: GLA:D Back Patient Outcomes

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Project abstract:

Background: Reassuring patient education and exercise therapy are widely recommended interventions for back pain in clinical guidelines. However, many patients are offered non-guideline endorsed options, and strategies for effective implementation of guideline-based care have not yet been developed. This protocol outlines the evaluation of a strategy for nationwide implementation of standardised patient education and exercise therapy for people with persistent or recurrent back pain in a hybrid implementation-effectiveness design. The strategy and the evaluation were planned using the framework of the Behaviour Change Wheel.

Methods: The main activity of the implementation strategy is a two-days course for physiotherapists and chiropractors in delivering patient education and exercise therapy that is aimed at supporting patient self-management. This comes with ready-to-use patient education materials and exercise programs. The clinical intervention is a group-based program consisting of two sessions of patient education and 8 weeks of supervised exercises. The program uses a cognitive-behavioural approach and the aim of the exercise component is to restore the patient's ability and confidence to move freely. The implementation process is evaluated in a dynamic process monitoring the penetration, adoption and fidelity of the clinical intervention. The clinical intervention and potential effect mechanisms will be evaluated at the patient-level using measures of knowledge, skills, beliefs, performance, self-efficacy and success in self-management. The education of clinicians will be evaluated via clinician-level outcomes, including the Pain Attitudes and Beliefs Scale, the Practitioner Confidence Scale, and the Determinants of Implementation Behaviour Questionnaire. Effects at a national level will be investigated via data from national registries of health care utilisation and sick-leave.

Discussion: This implementation-effectiveness study is designed to evaluate the process of implementing an evidence-based intervention for back pain. It will inform the development of strategies for implementing evidencebased care for musculoskeletal pain conditions, it will enhance the understanding of mechanisms for developing patient self-management skills, and it will demonstrate the outcomes that are achievable in everyday clinical practice.

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GLA:D Back Patient Outcomes

Data Collection

What data will you collect or create?

The project collect data on patients attending a GLA:D Back course, and the clinicians offering the course to them.

Data on patients:

- Contact information, demographics
- Patient reported health data connected to low back pain
- Clinician reported health data

Data on clinicians:

- Contact information, demographics, work place information
- Attitude towards back pain treatment

Please ask for the "GLAD Back variable list" for detailed information on each variable.

How will the data be collected or created?

Data is collected and stored during the collection period using REDCap made available by OPEN

Documentation and Metadata

What documentation and metadata will accompany the data?

Full logging of single data items during collection. I.e. time of data entry, identity of the user entering data and full logging of all subsequent handling.

Export from REDCap ensures metadata is kept as e.g. STATA codebooks.

Ethics and Legal Compliance

How will you manage any ethical issues?

The Regional Committees on Health Research Ethics for Southern Denmark have received the request below regarding notification of your study, which has received Case Number S-20172000-93.

Based on the information available, the Committee has decided that the project must not be notified to scientific ethical committee system, cf. § 14 1 of the Act on Scientific Ethics of health science research projects.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

SDU holds the GLA:D trademark which is managed by SDU RIO. Copyright and other IPR issues are not relevant.

Storage and Backup

How will the data be stored and backed up during the research?

During data collection data is continually stored and updated in REDCap, hosted by OPEN / Region of Southern Denmark.

Permanent storing and storing of temporary data sets will be on secure SharePoint provided by University of Southern Denmark

How will you manage access and security?

Both REDCap and SharePoint allows for detailed and differentiated user access.

Only project employees with need to access data will be given permission to do so.

Data sets for subprojects will be pseudonymized and minimized to contain only necessary information.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

All

What is the long-term preservation plan for the dataset?

Participants consent to our handling the data as long as it is relevant for ongoing projects.
Data will be safely stored on SharePoint

Data Sharing**How will you share the data?**

Secure SharePoint made available by University of Southern Denmark will be the site for sharing.
A data request form has to be completed to apply for data use.

Are any restrictions on data sharing required?

- Access to subproject data set requires a signed contract with the GLA:D Back Group
- Subproject data sets will be minimized to contain only necessary variables.
- Subproject data sets will be pseudonomized if possible.

Responsibilities and Resources**Who will be responsible for data management?**

Orla Lund Nielsen, Data Manager

What resources will you require to deliver your plan?

REDCap (already available)
SharePoint (Already available)