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## Evaluation of the strategy for implementing the GLA:D® programme in Switzerland - a study protocol

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**Evaluation of the strategy for implementing the GLA:D® programme in Switzerland - a study protocol.**

**Lea Ettlin<sup>1,2\*</sup>, Marina Bruderer- Hofstetter<sup>1</sup>, Olivier Gaugler<sup>1</sup>, Irina Nast<sup>1</sup>, Anne-Kathrin Rausch Osthoff<sup>1</sup>, Karin Niedermann<sup>1</sup>**

<sup>1</sup> Institute of Physiotherapy, School of Health Professions, Zurich University of Applied Sciences, Winterthur, Switzerland  
<sup>2</sup> Department of Health Sciences and Health Policy, University of Lucerne, Lucerne, Switzerland

**\* Correspondence:**  
Lea Ettlin  
xetl@zhaw.ch

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## Abstract

**Introduction:** International guidelines recommend the use of exercise, education and weight reduction, when appropriate, as first line treatment for the conservative management of knee osteoarthritis (OA). These guidelines have not been applied systematically in Switzerland, resulting in an evidence-performance gap. After analysis of available programmes, the GLA:D® programme was determined as the most applicable exercise and education programme for its implementation in Switzerland. The implementation of GLA:D® Switzerland OA was initiated to encourage the wider implementation of the clinical guideline recommendations and to improve conservative management of knee OA. The aim of this study protocol is to describe the evaluation of the implementation strategy and its impact on implementation, service and clinical outcomes; as well as to identify contributing barriers and facilitators.

**Methods and analysis:** The Implementation Research Logic Model (IRLM) will be used to evaluate the strategy and analyse its impact on the implementation outcomes by means of a mixed methods approach. This protocol outlines the proposed measures, data sources and strategies for the evaluation. Predefined implementation outcomes will help to identify the implementation impact and analyse barriers and facilitators systematically. The study population will be the health care professionals who are involved in the conservative management of knee OA in Switzerland, i.e., physiotherapists and medical doctors, and their patients.

### **Ethics and dissemination:**

The data registry containing data of patients participating in the GLA:D® Switzerland OA programme is declared as a quality project by the Zurich ethics committee and does not fall within the scope of the Swiss Human Research Act (BASEC-Nr. Req-2019-00274). However, all participants involved in the evaluation, will be asked to give informed written consent.

**Trial registration:** not applicable.

Article summary

Strengths and limitations

- The structured evaluation by the use of frameworks and implementation theories helps to determine the need for and the types of further implementation activities and can also be transferred to other project in chronic care management
- Participants/Patients are involved in the evaluation process to determine if the implementation is meeting their needs
- The mixed-methods approach helps to cover many facets for understanding the context and implementation barriers or facilitators
- There is no gold standard for the evaluation of implementation strategies and no clear-cut decision can be made on whether an implementation was successful
- The recruitment rate is yet unclear for survey participants or interview partners, however, in implementation studies the focus is not on sample size, but on selecting representative samples, i.e., assessing results in heterogeneous, unselected population and real-life clinical setting

Background

Exercise and education for knee osteoarthritis

Knee osteoarthritis (OA) represents a major burden both for the patient and the health care system (1,2). The international clinical guidelines of Osteoarthritis Research Society International (OARSI), European Alliance of Associations for Rheumatology (EULAR) and American College of Rheumatology (ACR) recommend exercise, education and, when appropriate, weight reduction as the first line intervention in the conservative management of knee OA (3–5). These interventions aim to improve knee OA-related symptoms and enhancing patients’ self-management (6). Exercise and education programmes for knee OA that translate the guideline recommendations into clinical practice have been shown to be feasible and effective (6–14). Some are endorsed by OARSI, e.g., ‘Better management of

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3 Patients with OsteoArthritis' (BOA), 'OsteoArthritis Chronic Care Program' (OACCP) or 'Good  
4 Life with osteoArthritis Denmark' (GLA:D®) (6,10,11). A prior analysis of the OARSI-approved  
5 programmes resulted in the GLA:D® programme as the most applicable exercise and  
6 education programme for implementation in Switzerland, since it had the highest congruency  
7 of settings and the highest chance for successful implementation (15).  
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### 13 14 **Implementation of an exercise and education programme in Switzerland** 15

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17 Knee OA is the most treated diagnosis in Swiss hospitals but, since patient data in an  
18 outpatient setting are not systematically collected, the prevalence and incidence of knee OA  
19 remain unclear and are mainly based on data from the inpatient setting (16). Therefore, a  
20 survey among medical specialists was performed to gain insight on the conservative  
21 management of knee OA in the outpatient setting of Switzerland (17). The results showed  
22 that the estimated referral rate to exercise was of some 54% only and, thus, indicated an  
23 evidence-performance gap in the conservative management of knee OA (17). The study  
24 demonstrated that guideline recommendations were not applied systematically in clinical  
25 practice and there was a need to implement a structured exercise and education programme  
26 to close this evidence-performance gap.  
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39 As a result, a network of physiotherapy experts in OA management founded the interest  
40 group 'IG GLA:D® Switzerland' in 2019 with the aim of implementing the GLA:D® programme  
41 in Switzerland. The IG consists of six research physiotherapists from three Universities of  
42 Applied Sciences in the German, French and Italian language areas of Switzerland, two  
43 clinical practitioners representing two specialist physiotherapy societies, and one patient  
44 representative of the Swiss League Against Rheumatism (SLAR). Programmes like GLA:D®  
45 apply standardized assessments and progress reports which can help to ascertain if the  
46 interventions help improving the participants' symptoms. The implementation of a new  
47 programme in a health care system is complex and involves multiple levels in the health care  
48 system and health care delivery (18). The impact of the implementation can be evaluated  
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through the measurement of implementation outcomes, combined with the effectiveness of the programme and the contextual factors that influence the outcomes (19).

**Aims and objectives**

To understand whether the GLA:D® Switzerland OA programme has been implemented appropriately, it is important to evaluate the impact of the implementation strategy itself and not only to focus on the programme’s effects, i.e., participants’ clinical outcomes (19–21). The impact of the implementation is conceptualized by various implementation outcomes (e.g. acceptability, appropriateness, feasibility, adoption, fidelity, penetration and sustainability) including the effectiveness of the programme (20). Therefore, the overall aim of this study is to describe the implementation strategy and the process how to evaluate its impact.

The specific aims of this evaluation are:

1. To evaluate the impact of implementation strategy of GLA:D® Switzerland OA based on the implementation outcomes and analyse the influencing factors (barriers and facilitators).
2. To analyse the effect of the implementation strategy on the provision of health service and clinical outcomes.

**Methods and analysis**

**Study design**

An implementation-effectiveness hybrid type 3 design with a mixed-methods approach will be employed (22).

The reporting of this study protocol follows the ‘Standards for Reporting Implementation studies’ (StaRI) statement.

**Evaluation framework**

This evaluation is guided by the Implementation Research Logic Model (IRLM), developed by Smith, Li and Rafferty (2020) (23). The IRLM is based on the theory that an implementation

strategy is dependent on specific implementation determinants, i.e., context-specific barriers and facilitators, and works through a specific mechanism of action to change the behaviours of the involved people within the context.

The IRLM format chosen for this evaluation comprises five foundational elements (see Fig. 1):

1. *Determinants* – the determinants used in the IRLM are based on the Consolidated Framework for Implementation Research (CFIR) and provide information on the potential barriers and facilitators in the five different IRLM domains, i.e., intervention characteristics, inner setting, outer setting, individual characteristics, and process. For each determinant, valence is noted to indicate the possible impact of the determinant on the implementation from +2 (strong positive = facilitator) to -2 (strong negative = barrier).
2. *Implementation Strategies* – the implementation strategies occur on multiple levels to support adoption into usual care. These strategies can be developed specifically for the implementation project, but can also be supported by ongoing strategies.
3. *Mechanism* - the mechanism of action, which can also be part of 'implementation strategy', has an influence on most of the implementation outcomes. It describes the process through which the strategy operates to affect the desired outcomes.
4. *Intervention* – the intervention elucidates the functionality of the programme that has been implemented.
5. *Outcomes* - the outcomes in the IRLM are subdivided into implementation, service, and clinical/patient outcomes. The implementation outcomes described by Proctor et al. (2011) include acceptability, appropriateness, feasibility, adoption, fidelity, penetration, and sustainability (20). The leading indicators for analysing implementation success, i.e., acceptability, appropriateness, and feasibility, are often evaluated during the implementation process to manage the strategies and predict future trends for the other outcomes (20). The outcomes are interdependent on each other and their results are influenced by the different 'Determinants', 'Implementation

strategies' and 'Mechanism' (22,23,26). The influences on the implementation outcomes acceptability, appropriateness, feasibility, adoption, fidelity, penetration, and sustainability are outlined with in supplement material 1.

Figure 1 shows the IRLM format with the five foundational elements and Figure 2 the IRLM applied for this project. The use of the IRLM elements in this implementation project are explained in detail in the subsequent sections.

➔ *Figure 1*

➔ *Figure 2*

*IRLM - Determinants*

The determinants of the implementation of exercise and education as first-line intervention are described in the five different domains. These determinants that act potentially as facilitators or barriers as indicated by valence, were examined in the early stage of the implementation process. This was firstly accomplished through surveys of medical doctors (specialists in general primary care, rheumatology, and orthopaedics) and of the physiotherapists (PTs) who attended the first GLA:D® certification courses. Additionally, contextual factors were analysed in a policy brief and a stakeholder dialogue (17,24,25).

*IRLM - Implementation strategies*

The guideline-based GLA:D® programme involves PTs and referring medical doctors working in a structured treatment pathway and applying their knowledge and skills within their professional roles. The establishment of a database for GLA:D®-related data allows standardised reporting of the individual participant's clinical outcomes and the monitoring of the overall quality of the programme.

For the implementation of the GLA:D® Switzerland OA programme there are several strategies being used. Representatives of three medical doctor and two physiotherapy scientific societies, of a patient organisation and an expert from physiotherapy research, are included as key stakeholders in the implementation process and their attitudes and points of view on a programme are assessed and considered carefully. To increase awareness and

acceptance, the programme is actively disseminated and promoted through various means and venues (e.g., information flyers and scientific presentations for health professionals; information flyers and mass media reports for the public), as well as through network building. PTs are the main target group of the strategy, since, after successful participation in the certification courses, they are the programme providers. This topic is described in more detail in 'mechanism of action'. The GLA:D® Switzerland OA programme is embedded within the reimbursement system for physiotherapy treatment, i.e., reimbursement of physiotherapy is covered by basic health insurance if referred by a medical doctor. Moreover, this project fits well to existing international and national ongoing strategies, which is beneficial to its implementation and funding: A) The implementation goals of this project are commensurate with the World Health Organisation (WHO) strategy 'Health 2020 and 2030' for the prevention and treatment of noncommunicable diseases (NCDs) (26). B) A national strategy for musculoskeletal diseases also exists, including one for OA management (27).

#### *IRLM - Mechanism*

The mechanism of action for GLA:D® Switzerland consists of three components: 1) certification courses for PTs; 2) the GLA:D® Switzerland OA programme for patients; and 3) data registry for quality monitoring.

*Certification course:* The attendance of the 2-day certification course allows Swiss PTs to offer the GLA:D® programme within their institutions. The course advances knowledge in the fields of OA and evidence-based treatment. It enables the ability to offer the specific GLA:D® educational and exercise sessions, perform the clinical tests and use the data registry. After successful completion of the certification course, PTs can implement GLA:D® Switzerland OA within their setting. The certificate is valid for 3 years and must be renewed thereafter.

*GLA:D® Switzerland OA programme:* The GLA:D® Switzerland OA programme includes: 1) an initial examination (e.g., medical history, personal factors, participant's characteristics), clinical tests, and data registry; 2) education sessions, with the goal that the participants understand the diagnosis and the management of OA; and 3) an evidence-based exercise

programme in which PTs can personalise the standardised exercises to the participants' needs.

*Data registry:* All demographic and clinical patient data are registered in a national database. The registry also includes participants' individual clinical outcomes and allows an evaluation of the quality of the treatment, e.g., standardised feedback or reports to the referring doctor, and the monitoring of the overall quality of the programme.

*IRLM - Intervention*

People with knee pain or diagnosed knee OA can participate in the programme. The programme consists of 1) three individual sessions for assessments at baseline and information/instruction of the standardised exercises; 2) two patient education sessions; and 3) twelve PT-supervised group exercise sessions. The baseline assessments are repeated during another individual session on completion of the programme. The predefined outcomes are assessed at the 12-month follow-up. The programme's goal is to enhance the patient's ability and skills to self-manage their health condition. Referring doctors receive a short, standardised report informing them of the intervention effect after completion of the programme.

*IRLM - Outcomes*

*Implementation outcomes:* Seven implementation outcomes will be used to analyse the success of the implementation strategy and to determine which factors influenced its success or failure (20). Both the implementation strategy and the mechanism of action can influence the implementation outcomes (23). The combination of all outcomes - implementation, service and clinical/patient - will indicate the implementation success of GLA:D® Switzerland OA.

*Service outcomes:* The annual report of GLA:D® Switzerland OA provides information on the service outcomes, such as equity or patient centredness (e.g., satisfaction). However, these outcomes will be analysed in more depth to determine whether GLA:D® Switzerland OA offers a good clinical pathway.

*Clinical/patient outcomes:* The programme's impact on the individual participant is evaluated systematically and a summary of the outcomes for all participants is reported annually.

### **Evaluation implementation strategy**

The primary and secondary evaluation outcomes relating to implementation, service and clinical/patient outcomes are described in Table 1.

#### *Primary outcome:*

The primary outcome will be the evaluation of the implementation impact of GLA:D® Switzerland OA by analysing various factors (acceptability, appropriateness, feasibility, adoption, fidelity, penetration and sustainability) together with the effectiveness of the programme (20). The extent of adoption and penetration is influenced by acceptability, appropriateness, feasibility and fidelity. The analysis will allow the prediction of the sustainability of the programme application and the drawing of conclusions on the implementation success.

#### *Secondary outcomes:*

1) Service outcomes will be analysed to determine whether GLA:D® Switzerland OA offers a good clinical pathway. The service outcomes are largely linked to barriers and facilitators on the level of 'intervention characteristics', but also to implementation strategies, e.g., utilisation of financial strategies, or reminding clinicians have an impact on service outcomes.

2) Clinical/patient outcomes are monitored systematically by the IG GLA:D® and reported annually on the website of GLA:D® Switzerland ([www.gladswitzerland.ch](http://www.gladswitzerland.ch)).

### **Study population**

The study population for this evaluation will consist of GLA:D®-certified and 'usual care' PTs, referring and non-referring primary care medical doctors, and GLA:D® participants. An analysis will be made of the proportional distribution of the representatives of their

stakeholder group, regarding their characteristics (e.g. age, gender, type of outpatient setting) in the three Swiss language areas, i.e., German, French and Italian.

**Patient and Public Involvement**

Patients or, in this case, GLA:D® participants, are actively involved in the implementation process and evaluation. In the stakeholder dialogue and other implementation activities the patients were represented by the SLAR. However, the implementation evaluation will include a patient survey to assess the implementation outcomes on the patient level and to see if the programme meets the patients' needs or if there are possible barriers for adoption of the programme.

**Data collection and analysis**

The evaluation will involve several data sources. Primary data sources are: 1) the data registry of GLA:D® participants, i.e. patients and GLA:D®-certified PTs; 2) data from surveys (Likert scales and open questions); and 3) qualitative data from in-depth interviews. Patient data in the registry will be assigned a study ID number and will be used anonymised for the evaluation. Data from the surveys and the qualitative data will also be anonymised through an assigned study ID number and stored on a local server. All survey participants and interview partners will be asked for permission to use their anonymised data through an informed consent. They will be apprised that participation is voluntary.

For assessing implementation success, surveys will be developed to empirically evaluate acceptability, appropriateness and feasibility in the various stakeholder groups, i.e., PTs, patients, medical doctors or institutions and clinics. For the evaluation of adoption, three implementation streams will be assessed, i.e., the number of: 1) medical doctors referring patients with OA to GLA:D® Switzerland OA; 2) PTs and organisations offering GLA:D® Switzerland OA; and 3) patients participating in the GLA:D® Switzerland OA programmes. A stratification question at the beginning of the surveys will be posed to ascertain whether the survey participant is still actively involved in GLA:D® Switzerland OA. The associated outcomes of adoption and penetration will both be analysed using data from the registry and

national statistical data. Fidelity will be tested through observation, based on predefined criteria on a standardised checklist. The outcome of sustainability is determined by the other implementation outcomes over time and, consequently, will be analysed at a later stage (minimum 4 years).

The surveys' responses and data from the registry will be quantitatively analysed and reported as frequencies, means and standard deviations. Subgroup analysis on participant characteristics (e.g., type of practice, age, profession, language area) will be performed to detect possible barriers to adoption or penetration. The characteristics of the GLA:D®-participating PTs, patients and medical doctors will be documented and compared for representativeness. Depending on data availability, the representativeness of the participating PTs, patients and medical doctors will be assessed through comparison with their non-participating associates.

The implementation outcomes will be evaluated further through (qualitative) in-depth analyses with selected PTs, patients, and medical doctors, where appropriate. The qualitative data will be anonymised, transcribed, and digitally recorded for subsequent analysis. These data can be used to explain the results of the surveys and the data registry, or for further exploration of barriers and facilitators. Moreover, they can also be employed to analyse service outcomes.

### *Secondary outcomes*

*The service outcome* of equity will be studied by analysing patient characteristics from the registry (i.e., age, gender, and region or language areas) and appropriate in-depth interviews. The patient survey will include questions on timeliness, patients' centredness, safety and efficiency. PTs will also be approached with a question in the survey on the complications of patient safety during their courses. The outcome of fidelity and appropriateness will provide information on patients' centredness and safety. These results may be further deepened by qualitative measures.

*Clinical/patient outcomes* are assessed for each patient participating in the programme. Pain, use of painkillers, functional ability, quality of life and satisfaction are measured within the programme. These outcomes are available from the data registry and are regularly analysed in the GLA:D®-programme annual report. Analysis of the annual reports will provide further explanations of the implementation outcomes.

**Table 1: Evaluation of primary and secondary outcomes - implementation, service, and clinical/patient-related outcomes**

Outcomes	Operationalisation	Indicator	Assessment
Acceptability	Perception that the programme offers a good pathway and acceptance to apply systematically as first line intervention	<ul style="list-style-type: none"> <li>- Willingness of PTs, patients and MDs to be involved in the programme</li> <li>- Acceptance of the systematic application of programme as first-line intervention in conservative management by PTs and MDs.</li> </ul>	Degree of acceptability of: <ul style="list-style-type: none"> <li>- content and delivery of GLA:D® Switzerland</li> <li>- certification courses (PTs)</li> <li>- process, including delivery organisation and complexity of assessments and data registry (MDs)</li> <li>- referring process and reporting (MDs)</li> </ul>
Appropriateness	Perceived fit (in the setting, with the current practice) or relevance of the programme for patients with knee OA.	<ul style="list-style-type: none"> <li>- Perceived fit of programme to provide good management for patients with knee OA</li> <li>- Perceived relevance of programme</li> <li>- Compatibility of programme with the setting and its usual care.</li> </ul>	Degree of perceived fit of: <ul style="list-style-type: none"> <li>- content and outcome of GLA:D® Switzerland</li> <li>- certification courses (PTs)</li> <li>- process, including delivery organisation and usefulness of a data registry in order to increase</li> </ul> Degree of compatibility of: <ul style="list-style-type: none"> <li>- certification courses</li> <li>- programme</li> <li>- administrative work with the current practice (PTs)</li> </ul> Degree to which GLA:D® Switzerland OA meets guidelines recommendations (PTs, patients, MDs)
Feasibility	Extent to which programme can be carried out easily and successfully in daily routine	<ul style="list-style-type: none"> <li>- Extent to which programme can be carried out easily in daily routine, e.g. complexity, adaptability, resource availability by PTs and patients</li> <li>- Extent to which programme can be used successfully in the physiotherapeutic context</li> <li>- Extent of the sufficiency of training / certification courses for the readiness to provide the programme regularly by PTs</li> <li>- Extent to which referral to the programme is feasible for MDs</li> </ul>	Degree of feasibility of GLA:D® Switzerland OA <ul style="list-style-type: none"> <li>- content, e.g. complexity and adaptability (PTs)</li> <li>- delivery, e.g. sufficiency of training and resources (patients)</li> <li>- performance for daily routine, e.g. sufficiency of resources (patients)</li> <li>- referral to GLA:D® Switzerland OA (MDs)</li> </ul>
Adoption	Application of the programme in the outpatient setting (PT practices, ambulatory of hospitals, clinics and nursing homes)	Absolute number, proportion, and representativeness of: <ul style="list-style-type: none"> <li>- PTs in outpatient setting (PT practices, ambulatory of hospitals, clinics and nursing homes) who were approached compared to the ones who are offering the programme</li> <li>- programme participants (increase over time, regional differences, dropouts)</li> <li>- referrals (increase over time, regional differences, characteristics of medical doctors, referral pattern over time)</li> <li>- clinics, hospitals, institutions, practices offering the programme (increase over time, regional differences)</li> </ul>	Total number of PTs, patients, MDs, and institutions involved in GLA:D® Switzerland OA, Proportion of patients, PTs, MDs, and institutions Analysis of adherence to programme until follow-up Analysis of characteristics, e.g. how many different types of institutions (MDs) Comparison of characteristics between participating institutions, clinics, practices, <i>depending on availability</i> Additional: Reasons for withdrawal – analysis of barriers and facilitators
Fidelity	Implementation of programme according to original protocol.	Degree to which programme has been implemented in participating PT practices as intended	Fidelity evaluation on 5 dimensions: <ul style="list-style-type: none"> <li>- adherence to programme protocol</li> <li>- programme component differentiation</li> <li>- participant responsiveness or involvement</li> <li>- dose or amount of programme delivered</li> <li>- quality of programme</li> </ul> Additional analysis of barriers and facilitators to implementation
Penetration	Institutionalisation or integration of the programme within the field of physiotherapy.	Absolute number of institutionalisations or integration of programme within the field of physiotherapy, institutions, clinics or practices. Proportion and representativeness of PTs or MDs	Number of GLA:D®-certified PTs delivering GLA:D® OA by the total number of PTs in Switzerland Number of MDs referring to GLA:D® OA Switzerland

		willing to be involved in the programme.	number of MDs (GPs, rheumatologists and orthopaedists) Ability to estimate and identify targeted patients including facilitators and barriers  Number of institutions, clinics or practices offering the programme total number of institutions, clinics or practices offering hip OA.
Sustainability	Maintenance of programme in the field of physiotherapy as usual care.	Diffusion of the programme in the field of physiotherapy and continuity of courses. Referral by MDs to programme as usual care for people with knee OA Integration of the programme into the organisational culture through policies and practices	- Systematic offers of GLAD® OA Switzerland in the region, number of courses, continuity (PTs, orthopaedists) - Systematic referral to GLAD® OA Switzerland, number of courses, continuity (MDs). - Exploration and evaluation of possible barriers (institutions, organisations) - Analysis of internal culture (organisation) - Number of patients undergoing surgery with GLAD® OA Switzerland versus usual care
<b>Secondary outcomes - service outcomes</b>			
Equity	Avoiding unconscious bias	Prevalence of patients participating in the programme based on age, gender, region. Reasons as to why eligible patients are not referred.	- Percentage of GLAD® OA Switzerland participants by age, gender, region (subgroup analysis) - Analysis of reasons, characteristics of eligible patients if possible
Timeliness	Reduced waiting time and avoidance of (harmful) delays	Time from identification (knee OA or knee pain) to programme	Number of months from identification of OA to start of programme in Switzerland
Patients centredness	Respectful care and responsiveness to patients' need and values	Patients' willingness to participate in programme and their satisfaction with content	Degree of satisfaction on: - content of GLA:D® Switzerland OA, i.e. education, understanding and knowledge gained)
Safety	Harm due to programme intervention	Records of complications within the programme	Number and type of incidences which led to patient withdrawal
Efficiency	Regional or waiting-related underuse	Optimal use of service, i.e. availability and accessibility of courses (e.g. region, waiting lists)	Regional distribution of courses Number of days/weeks from application until participation
<b>Secondary outcomes – clinical/patient outcomes</b>			
Clinical/patient outcomes	Improvement of OA-related symptoms, function and quality of life	Effectiveness of programmes, i.e. impact on pain, physical function and quality of life	- Percentage of pain reduction among all participants - Percentage of improvement in physical function - Percentage of improvement in quality of life (if possible)

PTs – Physiotherapists, MDs – Medical Doctors, OA – Osteoarthritis

## Discussion

The protocol describes the proposed measures, data sources and strategies to evaluate the impact of the GLA:D® Switzerland OA programme. The implementation strategy at the different levels aims to improve acceptability among the key stakeholders and, therefore, enhance adoption, penetration and, ideally, long-term sustainability. However, the implementation of a new programme is not a linear process and needs continuous evaluation. The predefined implementation outcomes will help to identify barriers and facilitators systematically, and to explain the reasons for the success or failure of specific elements of the implementation strategy. The results will feed into the planning of further implementation activities. Furthermore, they facilitate the determination of the factors that require more attention for the systematic application of the GLA:D® Switzerland OA programme.

The systematic implementation of the GLA:D® Switzerland OA programme was initiated to improve the conservative management of knee OA by closing the existing evidence-

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performance gap in Switzerland. GLA:D® is a so-called best-practice exercise and education programme that has already been successfully implemented in other countries. There is already strong evidence of its effectiveness (6,9,10). Quality improvements have already been made and lessons have been learned from prior implementations in other countries (6). This has helped in designing the implementation in Switzerland.

The original GLA:D® programme did not focus on weight reduction, but its inclusion could be of importance in the Swiss context, since some 42% and 11% of Swiss adults are considered overweight and obese, respectively, in the year 2020 (28). Weight reduction is also one of the first-line intervention recommendations in conservative knee OA management, since overweight and obesity are major risk factors for developing knee OA (1-5).

It is seen as a significant strength that the evaluation of the implementation of the GLA:D® Switzerland OA programme is based on the use of frameworks and implementation theories. These theories help to structure and guide the planning, execution and evaluation of an implementation project (23). A structured evaluation will be useful in determining the need for and the types of further implementation activities (20,23). Furthermore, the systematic and structured evaluation process, using the IRLM, can be transferred to the development or evaluation of implementation strategies of other projects in chronic care management. The inclusion of the major stakeholders, such as health care providers (PTs, referring doctors), their scientific and professional societies, as well as patients in the implementation process is necessary to understanding the reasons, including facilitators and barriers for adoption, penetration and sustainability. The mixed-methods approach helps to cover many facets for understanding the context and implementation barriers or facilitators.

Evaluation studies have often described 'lessons learned', meaning barriers or facilitators that have emerged during an implementation process (6). To date, no gold standard exists for the evaluation of implementation strategies and no clear-cut decision can be made on whether an implementation was successful (20). Thus, this evaluation of the implementation impact will be the result of combining numerous outcomes with pragmatic explanations of its

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3 success or failure in a certain context (20). It is yet unclear how many survey participants or  
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5 interview partners will be recruited, however, in contrast to previously defined sample sizes in  
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7 clinical trials, in implementation studies the focus is on selecting representative samples.  
8  
9 Therefore, assessing results in heterogeneous, unselected population and real-life clinical  
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11 setting are important considerations when analysing the representativeness of the results  
12  
13 (29).  
14

## 15 16 17 **Conclusion**

18  
19 This study protocol for the evaluation of an implementation strategy will help to monitor  
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21 systematically the impact of the implementation of GLA:D® Switzerland OA and to  
22  
23 continuously identify and address its barriers and facilitators. The results of the evaluation  
24  
25 will assist in determining how the programme contributes to the overall goal of improving the  
26  
27 conservative non-pharmacological management of patients with knee OA in Switzerland.  
28  
29 Moreover, the acquired knowledge and lessons learned regarding implementation in this  
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31 study might also be transferred to other implementation projects in the field of chronic care  
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33 management.  
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## 36 37 38 39 **Ethical and dissemination**

40  
41 The data registry containing data of patients participating in the GLA:D® Switzerland OA  
42  
43 programme is declared as a quality project by the Zurich ethics committee and does not fall  
44  
45 within the scope of the Swiss Human Research Act (BASEC-Nr. Req-2019-00274). However,  
46  
47 all participants involved in the evaluation, will be asked to give informed written consent.  
48  
49

## 50 51 **Authors' contributions**

52  
53 LE and KN conceptualized and designed the study protocol and drafted the manuscript. All  
54  
55 authors revised and approved the manuscript for publication.

## 56 57 **Competing interests**

58  
59 KN is head of research GLA:D® Switzerland OA.

60  
The symbol ® in GLA:D® stands for 'quality-controlled programme', with no commercial interests.

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**Word count**

3376

**Figures**

*Figure 1: Implementation Research Logic Model (IRLM) by Smith et al. (2020) (23)*

*Figure 2: Implementation Research Logic Model (IRLM) used for the implementation of GLA:D® Switzerland OA*

EBI – Evidence-Based Intervention; PTs – Physiotherapists; MDs – Medical Doctor, IG GLA:D® - Interest Group GLA:D® Switzerland; NCD – Non-Communicable Disease; WHO – World Health Organisation; SLR- Swiss League against Rheumatism; OA – Osteoarthritis

Figure 1: Implementation Research Logic Model (IRLM) by Smith et al. (2020) (23)

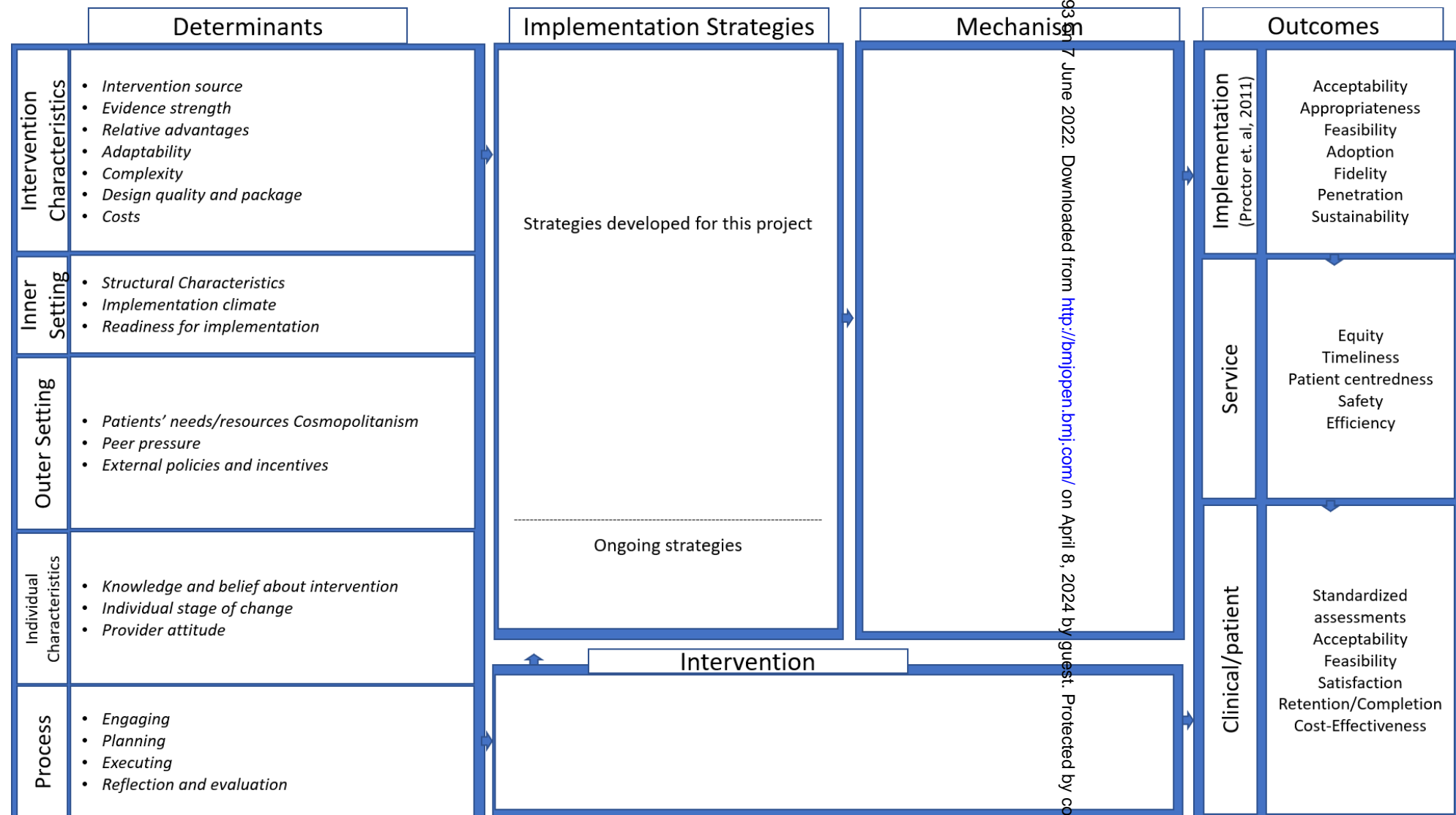
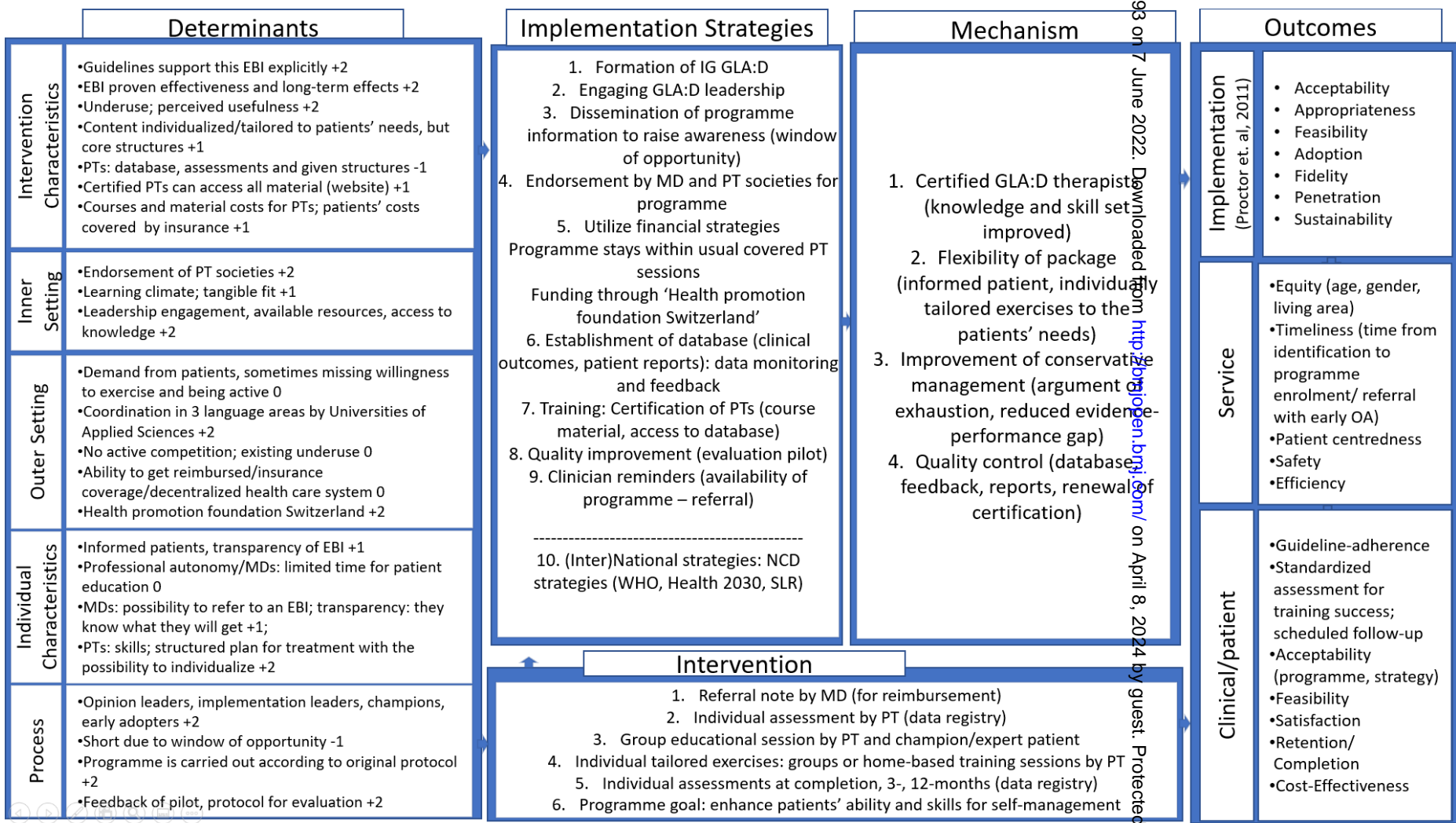


Figure 2: Implementation Research Logic Model (IRLM) used for the implementation of GLA:D® Switzerland OA



EBI – Evidence-Based Intervention; PTs – Physiotherapists; MDs – Medical Doctor, IG GLA:D® - Interest Group GLA:D® Switzerland; NCD – Non-Communicable Disease; WHO – World Health Organisation; SLR- Swiss League against Rheumatism; OA – Osteoarthritis

## Supplement I: Matrix of the influences on the implementation outcomes

	Acceptability	Appropriateness	Feasibility	Adoption	Fidelity	Penetration	Sustainability
<b>Determinants</b>							
Guidelines support this EBI explicitly	X	X					
EBI proven effectiveness and long-term effect	X	X					
Underuse; perceived usefulness	X	X					
Content individualized/tailored to patients' needs, but core structure	X	X	X				
PTs: database, assessments and given structures	X	X	X				
Certified PTs can access all material (website)	X	X	X				
Courses and material costs for PTs; patients' costs covered by insurance	X	X	X				
Endorsement of PT societies	X						
Learning climate, tangible fit	X						
Leadership engagement, available resources, access to knowledge	X						
Demand from patients, sometimes missing willingness to exercise and being active	X	X					
Coordination in 3 language areas by Universities of Applied Sciences	X						
Informed patients, transparency of EBI	X	X					
Professional autonomy/MDs: limited time for patient education	X						
MDs: possibility to refer to an EBI; transparency: they know what they will get	X	X					
PTs: skills; structured plan for treatment with the possibility to individualize	X	x					
<b>Implementation Strategies</b>							
Formation of IG GLA:D							
Dissemination of programme information to raise awareness (window of opportunity)	X	x		X		X	
Endorsement by MD and PT societies for programme	X	x		X			X
Utilize financial strategies	X	x		X		X	X

Programme stays within usual covered PT sessions							
Establishment of database (clinical outcomes, patient reports): data monitoring and feedback							X
Training: Certification of PTs (course material, access to database)	X			X		X	
Quality improvement (evaluation first courses)	X			X		X	
Clinician reminders (availability of programme – referral)	X			X			X
(Inter)National strategies: NCD strategies (WHO, Health 2030, SLR)	X			X		X	X
Mechanism	x			x		X	



## Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies ([StaRI](#)) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies ([StaRI](#)). [Explanation and Elaboration document](#). *BMJ Open* 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			“Implementation strategy” refers to how the intervention was implemented		“Intervention” refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	1	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	2	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	3	3/4	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	4	3/4	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).		The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

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Aims and objectives	5	5	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	6	5	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	7	3/4/7	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	8	10	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.		The population targeted by the intervention and any eligibility criteria.
Description	9	7/8	A description of the implementation strategy		A description of the intervention
Sub-groups	10	11	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	11	10	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets		Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	12	10	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	13	na	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy		Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	14	na	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	15	11/12	Methods of analysis (with reasons for that choice)		
Sub-group analyses	16	11/12	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

Results					
Characteristics	17	na	Proportion recruited and characteristics of the recipient population for the implementation strategy		Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	18	na	Primary and other outcome(s) of the implementation strategy		Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	19	na	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	20	na	Resource use, costs, economic outcomes and analysis for the implementation strategy		Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	21	na	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/adaptation	22	na	Fidelity to implementation strategy as planned and adaptation to suit context and preferences		Fidelity to delivering the core components of intervention (where measured)
Contextual changes	23	na	Contextual changes (if any) which may have affected outcomes		
Harms	24	na	All important harms or unintended effects in each group		
Discussion					
Structured discussion	25	13/14	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	26	14	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)		Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	27	17	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

# BMJ Open

## Evaluation of the strategy for implementing the GLA:D® programme in Switzerland - a study protocol

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**Evaluation of the strategy for implementing the GLA:D® programme in Switzerland - a study protocol.**

**Lea Ettlin<sup>1,2\*</sup>, Marina Bruderer- Hofstetter<sup>1</sup>, Olivier Gaugler<sup>1</sup>, Irina Nast<sup>1</sup>, Anne-Kathrin Rausch Osthoff<sup>1</sup>, Karin Niedermann<sup>1</sup>**

<sup>1</sup> Institute of Physiotherapy, School of Health Professions, Zurich University of Applied Sciences, Winterthur, Switzerland  
<sup>2</sup> Department of Health Sciences and Health Policy, University of Lucerne, Lucerne, Switzerland

**\* Correspondence:**  
Lea Ettlin  
xetl@zhaw.ch

**Keywords (3-10):** Exercise and education programmes; Implementation; Knee Osteoarthritis; IRLM; Evaluation; Study protocol.

## Abstract

**Introduction:** International guidelines recommend the use of exercise, education and weight reduction, when appropriate, as first line treatment for the conservative management of knee osteoarthritis (OA). These guidelines have not been applied systematically in Switzerland, resulting in an evidence-performance gap. After analysis of available programmes, the GLA:D® programme was determined as the most applicable exercise and education programme for its implementation in Switzerland. The implementation of GLA:D® Switzerland OA was initiated to encourage the wider implementation of the clinical guideline recommendations and to improve conservative management of knee OA. The aim of this study protocol is to describe the evaluation of the implementation strategy and its impact on implementation, service and clinical outcomes; as well as to identify contributing barriers and facilitators.

**Methods and analysis:** The Implementation Research Logic Model (IRLM) will be used to evaluate the strategy and analyse its impact on the implementation outcomes by means of a mixed methods approach. This protocol outlines the proposed measures, data sources and strategies for the evaluation. Predefined implementation outcomes will help to identify the implementation impact and analyse barriers and facilitators systematically. The study population will be the health care professionals who are involved in the conservative management of knee OA in Switzerland, i.e., physiotherapists and medical doctors, and their patients.

### **Ethics and dissemination:**

The data registry containing data of patients participating in the GLA:D® Switzerland OA programme is declared as a quality project by the Zurich ethics committee and does not fall within the scope of the Swiss Human Research Act (BASEC-Nr. Req-2019-00274). However, all participants involved in the evaluation, will be asked to give informed written consent.

**Trial registration:** not applicable.

### **Article summary**

**Strengths and limitations**

- The structured evaluation by the use of frameworks and implementation theories helps to determine the need for and the types of further implementation activities and can also be transferred to other project in chronic care management
- Participants/Patients are involved in the evaluation process to determine if the implementation is meeting their needs
- The mixed-methods approach helps to cover many facets for understanding the context and implementation barriers or facilitators
- There is no gold standard for the evaluation of implementation strategies and no clear-cut decision can be made on whether an implementation was successful
- The recruitment rate is yet unclear for survey participants or interview partners, however, in implementation studies the focus is not on sample size, but on selecting representative samples, i.e., assessing results in heterogeneous, unselected population and real-life clinical setting

**Introduction**

**Exercise and education for knee osteoarthritis**

Knee osteoarthritis (OA) represents a major burden both for the patient and the health care system (1,2). The international clinical guidelines of Osteoarthritis Research Society International (OARSI), European Alliance of Associations for Rheumatology (EULAR) and American College of Rheumatology (ACR) recommend exercise, education and, when appropriate, weight reduction as the first line intervention in the conservative management of knee OA (3–5). These interventions aim to improve knee OA-related symptoms and enhancing patients’ self-management (6). Exercise and education programmes for knee OA that translate the guideline recommendations into clinical practice have been shown to be feasible and effective (6–14). Some are endorsed by OARSI, e.g., ‘Better management of Patients with OsteoArthritis’ (BOA), ‘OsteoArthritis Chronic Care Program’ (OACCP) or ‘Good Life with

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3 osteoArthritis Denmark' (GLA:D®) (6,10,11). A prior analysis of the OARSI-approved  
4 programmes resulted in the GLA:D® programme as the most applicable exercise and  
5 education programme for implementation in Switzerland, since it had the highest congruency  
6 of settings and the highest chance for successful implementation (15).  
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### 11 12 **Implementation of an exercise and education programme in Switzerland** 13

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15 Knee OA is the most treated diagnosis in Swiss hospitals but, since patient data in an  
16 outpatient setting are not systematically collected, the prevalence and incidence of knee OA  
17 remain unclear and are mainly based on data from the inpatient setting (16). However, even  
18 though data from the outpatient setting is missing, clinical observations and the high number  
19 of surgeries indicated that the prevalence of knee OA is high. Therefore, a survey among  
20 medical specialists, working in primary care, was performed to gain insight on the conservative  
21 management of knee OA in the outpatient setting of Switzerland (17). The results showed that  
22 the estimated referral rate to exercise was of some 54% only and, thus, indicated an evidence-  
23 performance gap in the conservative management of knee OA (17). The study demonstrated  
24 that guideline recommendations were not applied systematically in clinical practice and there  
25 was a need to implement a structured exercise and education programme to close this  
26 evidence-performance gap. Furthermore, there is missing transparency in the management of  
27 knee OA assuming that patients with knee OA are usually treated with hands-on techniques in  
28 physiotherapy. An exercise and education programme might help to systematically translate  
29 the guideline recommendations into practice.  
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47 As a result, a network of physiotherapy experts in OA management founded the interest group  
48 'IG GLA:D® Switzerland' in 2019 with the aim of implementing the GLA:D® programme in  
49 Switzerland. The IG consists of six research physiotherapists from three Universities of Applied  
50 Sciences in the German, French and Italian language areas of Switzerland, two clinical  
51 practitioners representing two specialist physiotherapy societies, and one patient  
52 representative of the Swiss League Against Rheumatism (SLAR). Programmes like GLA:D®  
53 apply standardized assessments and progress reports which can help to ascertain if the  
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interventions help improving the participants' symptoms. GLA:D® is a treatment concept for OA, developed by the university of Southern Denmark, and is being implemented internationally. Therefore, its adaptability to personal or nation-specific needs is limited to guarantee, that GLA:D® is the same to patients and other stakeholders wherever it is provided (11). However, the implementation of a new programme in a health care system is complex and involves multiple levels in the health care system and health care delivery (18). The impact of the implementation can be evaluated through the measurement of implementation outcomes, combined with the effects of the programme and the contextual factors that influence the outcomes (19).

**Aims and objectives**

To understand whether the GLA:D® Switzerland OA programme has been implemented appropriately, it is important to evaluate the impact of the implementation strategy itself and not only to focus on the programme's effects, i.e., participants' clinical outcomes (19–21). The impact of the implementation is conceptualized by various implementation outcomes (e.g. acceptability, appropriateness, feasibility, adoption, fidelity, penetration and sustainability) including the effects of the programme (20). Therefore, the overall aim of this study is to describe the implementation strategy and the process how to evaluate its impact.

The specific aims of this evaluation are:

1. To evaluate the impact of implementation strategy of GLA:D® Switzerland OA based on the implementation outcomes and analyse the influencing factors (barriers and facilitators).
2. To analyse the effect of the implementation strategy on the provision of health service and clinical outcomes.

**Methods and analysis**

**Study design**

An implementation-effectiveness hybrid type 3 design with a mixed-methods approach will be employed (22).

The reporting of this study protocol follows the 'Standards for Reporting Implementation studies' (StaRI) statement.

### **Evaluation framework**

This evaluation is guided by the Implementation Research Logic Model (IRLM), developed by Smith, Li and Rafferty (2020) (23). The IRLM is based on the theory that an implementation strategy is dependent on specific implementation determinants, i.e., context-specific barriers and facilitators, and works through a specific mechanism of action to change the behaviours of the involved people within the context.

The IRLM format chosen for this evaluation comprises five foundational elements (see Fig. 1):

1. *Determinants* – the determinants used in the IRLM are based on the Consolidated Framework for Implementation Research (CFIR) and provide information on the potential barriers and facilitators in the five different IRLM domains, i.e., intervention characteristics, inner setting, outer setting, individual characteristics, and process. For each determinant, valence is noted to indicate the possible impact of the determinant on the implementation from +2 (strong positive = facilitator) to -2 (strong negative = barrier).
2. *Implementation Strategies* – the implementation strategies occur on multiple levels to support adoption into usual care. These strategies can be developed specifically for the implementation project, but can also be supported by ongoing strategies.
3. *Mechanism* - the mechanism of action, which can also be part of 'implementation strategy', has an influence on most of the implementation outcomes. It describes the process through which the strategy operates to affect the desired outcomes.
4. *Intervention* – the intervention elucidates the functionality of the programme that has been implemented.
5. *Outcomes* - the outcomes in the IRLM are subdivided into implementation, service, and clinical/patient outcomes. The implementation outcomes described by Proctor et al. (2011) include acceptability, appropriateness, feasibility, adoption, fidelity, penetration, and sustainability (20). The leading indicators for analysing implementation success,

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i.e., acceptability, appropriateness, and feasibility, are often evaluated during the implementation process to manage the strategies and predict future trends for the other outcomes (20). The outcomes are interdependent on each other and their results are influenced by the different ‘Determinants’, ‘Implementation strategies’ and ‘Mechanism’ (22,23,26). The influences on the implementation outcomes acceptability, appropriateness, feasibility, adoption, fidelity, penetration, and sustainability are outlined with in supplement material 1.

Figure 1 shows the IRLM format with the five foundational elements and Figure 2 the IRLM applied for this project. The use of the IRLM elements in this implementation project are explained in detail in the subsequent sections.

- ➔ *Figure 1*
- ➔ *Figure 2*

*IRLM - Determinants*

The determinants of the implementation of exercise and education as first-line intervention are described in the five different domains. These determinants that act potentially as facilitators or barriers as indicated by valence, were examined in the early stage of the implementation process. This was firstly accomplished through surveys of medical doctors (specialists in general primary care, rheumatology, and orthopaedics) and of the physiotherapists (PTs) who attended the first GLA:D® certification courses. Additionally, contextual factors were analysed in a policy brief and a stakeholder dialogue (17,24,25).

*IRLM - Implementation strategies*

The guideline-based GLA:D® programme involves PTs and referring medical doctors working in a structured treatment pathway and applying their knowledge and skills within their professional roles. The establishment of a database for GLA:D®-related data allows standardised reporting of the individual participant’s clinical outcomes and the monitoring of the overall quality of the programme.

For the implementation of the GLA:D® Switzerland OA programme there are several strategies being used. Representatives of three medical doctor and two physiotherapy scientific societies, of a patient organisation and an expert from physiotherapy research, are included as key stakeholders in the implementation process and their attitudes and points of view on a programme are assessed and considered carefully. To increase awareness and acceptance, the programme is actively disseminated and promoted through various means and venues (e.g., information flyers and scientific presentations for health professionals; information flyers and mass media reports for the public), as well as through network building. Medical specialists and PTs are the main target groups of the strategy. Medical specialists can refer the patients to the programme and therefore, have to be aware of and accept the programme. PTs, are also an important target group, since, after successful participation in the certification courses, they are the programme providers. This topic is described in more detail in 'mechanism of action'. The GLA:D® Switzerland OA programme is embedded within the reimbursement system for physiotherapy treatment, i.e., reimbursement of physiotherapy is covered by basic health insurance if referred by a medical doctor. Moreover, this project fits well to existing international and national ongoing strategies, which is beneficial to its implementation and funding: A) The implementation goals of this project are commensurate with the World Health Organisation (WHO) strategy 'Health 2020 and 2030' for the prevention and treatment of noncommunicable diseases (NCDs) (26). B) A national strategy for musculoskeletal diseases also exists, including one for OA management (27).

#### *IRLM - Mechanism*

The mechanism of action for GLA:D® Switzerland consists of three components: 1) certification courses for PTs; 2) the GLA:D® Switzerland OA programme for patients; and 3) data registry for quality monitoring.

**Certification course:** The attendance of the 2-day certification course allows Swiss PTs to offer the GLA:D® programme within their institutions. The course advances knowledge in the fields of OA and evidence-based treatment. It enables the ability to offer the specific GLA:D® educational and exercise sessions, perform the clinical tests and use the data registry. After

successful completion of the certification course, PTs can implement GLA:D® Switzerland OA within their setting. The certificate is valid for 3 years and must be renewed thereafter.

*GLA:D® Switzerland OA programme:* The GLA:D® Switzerland OA programme includes: 1) an initial examination (e.g., medical history, personal factors, participant’s characteristics), clinical tests, and data registry; 2) education sessions, with the goal that the participants understand the diagnosis and the management of OA; and 3) an evidence-based exercise programme in which PTs individually tailor the standardised exercises to the participants’ needs.

*Data registry:* All demographic and clinical patient data are registered in a national database. The registry also includes participants’ individual clinical outcomes and allows an evaluation of the quality of the treatment, e.g., standardised feedback or reports to the referring doctor, and the monitoring of the overall quality of the programme.

*IRLM - Intervention*

People with knee pain or diagnosed knee OA can participate in the programme. The programme consists of 1) three individual sessions for assessments at baseline and information/instruction of the standardised and individually tailored exercises; 2) two patient education sessions; and 3) twelve PT-supervised group exercise sessions where the exercises are continuously and individually adapted with regard to dose and difficulty. The baseline assessments are repeated during another individual session on completion of the programme. The predefined outcomes are assessed at the 12-month follow-up. The programme’s goal is to enhance the patient’s ability and skills to self-manage their health condition. Referring doctors receive a short, standardised report informing them of the intervention effect after completion of the programme.

*IRLM - Outcomes*

*Implementation outcomes:* Seven implementation outcomes will be used to analyse the success of the implementation strategy and to determine which factors influenced its success or failure (20). Both the implementation strategy and the mechanism of action can influence

the implementation outcomes (23). The combination of all outcomes - implementation, service and clinical/patient - will indicate the implementation success of GLA:D® Switzerland OA.

*Service outcomes:* The annual report of GLA:D® Switzerland OA provides information on the service outcomes, such as equity or patient centredness (e.g., satisfaction). However, these outcomes will be analysed in more depth to determine whether GLA:D® Switzerland OA offers a good clinical pathway.

*Clinical/patient outcomes:* The programme's impact on the individual participant is evaluated systematically and a summary of the outcomes for all participants is reported annually.

### **Evaluation implementation strategy**

The primary and secondary evaluation outcomes relating to implementation, service and clinical/patient outcomes are described in Table 1.

#### *Primary outcome:*

The primary outcome will be the evaluation of the implementation impact of GLA:D® Switzerland OA by analysing various factors (acceptability, appropriateness, feasibility, adoption, fidelity, penetration and sustainability) together with the effectiveness of the programme (20). The extent of adoption and penetration is influenced by acceptability, appropriateness, feasibility and fidelity. The analysis will allow the prediction of the sustainability of the programme application and the drawing of conclusions on the implementation success.

#### *Secondary outcomes:*

1) Service outcomes will be analysed to determine whether GLA:D® Switzerland OA offers a good clinical pathway. The service outcomes are largely linked to barriers and facilitators on the level of 'intervention characteristics', but also to implementation strategies, e.g., utilisation of financial strategies, or reminding clinicians have an impact on service outcomes.

2) Clinical/patient outcomes are monitored systematically by the IG GLA:D® and reported annually on the website of GLA:D® Switzerland ([www.gladswitzerland.ch](http://www.gladswitzerland.ch)). This will help to make sure that the programme’s effects are not compromised through the process of implementation (22).

**Study population**

The study population for this evaluation will consist of GLA:D®-certified and ‘usual care’ PTs, referring and non-referring primary care medical doctors, and GLA:D® participants. An analysis will be made of the proportional distribution of the representatives of their group, regarding their characteristics (e.g. age, gender, type of outpatient setting) in the three Swiss language areas, i.e., German, French and Italian

**Patient and Public Involvement**

Patients or, in this case, GLA:D® participants, are actively involved in the implementation process and evaluation. In the stakeholder dialogue and other implementation activities the patients were represented by the SLAR. However, the implementation evaluation will include a patient survey to assess the implementation outcomes on the patient level and to see if the programme meets the patients’ needs or if there are possible barriers for adoption of the programme.

**Data collection and analysis**

The evaluation will involve several data sources. Primary data sources are: 1) the data registry of GLA:D® participants, i.e. patients and GLA:D®-certified PTs; 2) data from surveys (Likert scales and open questions) with representative samples, i.e. as far as possible all who participate in/refer to/ provide the GLA:D® programme during a certain time period. Furthermore, a representative number of patients, PTs, medical specialists, depending on the number of people supporting GLAD, who do not support the programme; and 3) qualitative data from in-depth interviews. For the interviews, data saturation will indicate when there are enough participants. Patient data in the registry will be assigned a study ID number and will be used anonymised for the evaluation. Data from the surveys and the qualitative data will also

be anonymised through an assigned study ID number and stored on a local server. All survey participants and interview partners will be asked for permission to use their anonymised data through an informed consent. They will be apprised that participation is voluntary.

For assessing implementation success, surveys will be developed to empirically evaluate acceptability, appropriateness and feasibility in the various stakeholder groups, i.e., PTs, patients, medical doctors or institutions and clinics. For the evaluation of adoption, three implementation streams will be assessed, i.e., the number of: 1) medical doctors referring patients with OA to GLA:D® Switzerland OA; 2) PTs and organisations offering GLA:D® Switzerland OA; and 3) patients participating in the GLA:D® Switzerland OA programmes. A stratification question at the beginning of the surveys will be posed to ascertain whether the survey participant is still actively involved in GLA:D® Switzerland OA. The associated outcomes of adoption and penetration will both be analysed using data from the registry and national statistical data. Fidelity will be tested through observation, based on predefined criteria on a standardised checklist. The outcome of sustainability is determined by the other implementation outcomes over time and, consequently, will be analysed at a later stage (minimum 4 years).

The surveys' responses and data from the registry will be quantitatively analysed and reported as frequencies, means and standard deviations. Subgroup analysis on participant characteristics (e.g., type of practice, age, profession, language area) will be performed to detect possible barriers to adoption or penetration. The characteristics of the GLA:D®-participating PTs, patients and medical doctors will be documented and compared for representativeness. Depending on data availability, the representativeness of the participating PTs, patients and medical doctors will be assessed through comparison with their non-participating associates.

The implementation outcomes will be evaluated further through (qualitative) in-depth analyses with selected PTs, patients, and medical doctors, where appropriate. The qualitative data will be anonymised, transcribed, and digitally recorded for subsequent analysis. These data can

be used to explain the results of the surveys and the data registry, or for further exploration of barriers and facilitators. Moreover, they can also be employed to analyse service outcomes.

Secondary outcomes

The service outcome of equity will be studied by analysing patient characteristics from the registry (i.e., age, gender, and region or language areas) and appropriate in-depth interviews. The patient survey will include questions on timeliness, patients' centredness, safety and efficiency. PTs will also be approached with a question in the survey on the complications of patient safety during their courses. The outcome of fidelity and appropriateness will provide information on patients' centredness and safety. These results may be further deepened by qualitative measures.

Clinical/patient outcomes are assessed for each patient participating in the programme. Pain, use of painkillers, functional ability, quality of life and satisfaction are measured within the programme. These outcomes are available from the data registry and are regularly analysed in the GLA:D®-programme annual report. Analysis of the annual reports will provide further explanations of the implementation outcomes.

Table 1: Evaluation of primary and secondary outcomes - implementation, service, and clinical/patient-related outcomes

Outcomes	Operationalisation	Indicator	Assessment
Acceptability	Perception that the programme offers a good pathway and acceptance to apply systematically as first line intervention	<ul style="list-style-type: none"><li>- Willingness of PTs, patients and MDs to be involved in the programme</li><li>- Acceptance of the systematic application of programme as first-line intervention in conservative management by PTs and MDs.</li></ul>	Degree of acceptability of: <ul style="list-style-type: none"><li>- content and delivery of GLA:D® Switzerland</li><li>- certification courses (PTs)</li><li>- process, including delivery organisation and complexity of assessments and data registry</li><li>- referring process and reporting (MDs)</li></ul>
Appropriateness	Perceived fit (in the setting, with the current practice) or relevance of the programme for patients with knee OA.	<ul style="list-style-type: none"><li>- Perceived fit of programme to provide good management for patients with knee OA</li><li>- Perceived relevance of programme</li><li>- Compatibility of programme with the setting and its usual care.</li></ul>	Degree of perceived fit of: <ul style="list-style-type: none"><li>- content and outcome of GLA:D® Switzerland</li><li>- certification courses (PTs)</li><li>- process, including delivery organisation and usefulness of a data registry in order to increase</li></ul> Degree of compatibility of: <ul style="list-style-type: none"><li>- certification courses</li><li>- programme</li><li>- administrative work with the current practice (PTs)</li></ul> Degree to which GLA:D® Switzerland OA meets guidelines recommendations (PTs, patients, MDs)
Feasibility	Extent to which programme can be carried out easily and successfully in daily routine	<ul style="list-style-type: none"><li>- Extent to which programme can be carried out easily in daily routine, e.g. complexity, adaptability, resource availability by PTs and patients</li><li>- Extent to which programme can be used successfully in the physiotherapeutic context</li></ul>	Degree of feasibility of GLA:D® Switzerland OA: <ul style="list-style-type: none"><li>- content, e.g. complexity and adaptability (PTs)</li><li>- delivery, e.g. sufficiency of training and resources (patients)</li><li>- performance for daily routine, e.g. sufficiency of resources (patients)</li><li>- referral to GLA:D® Switzerland OA (MDs)</li></ul>

		- Extent of the sufficiency of training / certification courses for the readiness to provide the programme regularly by PTs - Extent to which referral to the programme is feasible for MDs	
Adoption	Application of the programme in the outpatient setting (PT practices, ambulatory of hospitals, clinics and nursing homes)	Absolute number, proportion, and representativeness of: - PTs in outpatient setting (PT practices, ambulatory of hospitals, clinics and nursing homes) who were approached compared to the ones who are offering the programme - programme participants (increase over time, regional differences, dropouts) - referrals (increase over time, regional differences, characteristics of medical doctors, referral pattern over time) - clinics, hospitals, institutions, practices offering the programme (increase over time, regional differences)	Total number of PTs, patients, MDs, and inst involved in GLA:D® Switzerland OA, Proport Analysis of adherence to programme until fo Analysis of characteristics, e.g. how many di pattern over time (MDs) Comparison of characteristics between partic institutions, clinics, practices, <i>depending on</i>  Additional: Reasons for withdrawal – analys
Fidelity	Implementation of programme according to original protocol.	Degree to which programme has been implemented in participating PT practices as intended	Fidelity evaluation on 5 dimensions: - adherence to programme protocol - programme component differentiation - participant responsiveness or involvement - dose or amount of programme delivered - quality of programme  Additional analysis of barriers and facilitators
Penetration	Institutionalisation or integration of the programme within the field of physiotherapy.	Absolute number of institutionalisations or integration of programme within the field of physiotherapy, institutions, clinics or practices. Proportion and representativeness of PTs or MDs willing to be involved in the programme.	Number of GLA:D®-certified PTs delivering G by the total number of PTs in Switzerland  Number of MDs referring to GLAD® OA Switz number of MDs (GPs, rheumatologists and d Ability to estimate and identify targeted patie including facilitators and barriers  Number of institutions, clinics or practices off total number of institutions, clinics or practice hip OA.
Sustainability	Maintenance of programme in the field of physiotherapy as usual care.	Diffusion of the programme in the field of physiotherapy and continuity of courses. Referral by MDs to programme as usual care for people with knee OA Integration of the programme into the organisational culture through policies and practices	- Systematic offers of GLAD® OA Switzerland region, number of courses, continuity (PTs, d - Systematic referral to GLAD® OA Switzerland number of courses, continuity (MDs). - Exploration and evaluation of possible barr organisations) - Analysis of internal culture (organisation) - Number of patients undergoing surgery with GLAD® OA Switzerland versus usual care
<b>Secondary outcomes - service outcomes</b>			
Equity	Avoiding unconscious bias	Prevalence of patients participating in the programme based on age, gender, region. Reasons as to why eligible patients are not referred.	- Percentage of GLAD® OA Switzerland part gender, region (subgroup analysis) - Analysis of reasons, characteristics of eligib if possible
Timeliness	Reduced waiting time and avoidance of (harmful) delays	Time from identification (knee OA or knee pain) to programme	Number of months from identification of OA t Switzerland
Patients centredness	Respectful care and responsiveness to patients' need and values	Patients' willingness to participate in programme and their satisfaction with content	Degree of satisfaction on: - content of GLA:D® Switzerland OA, i.e. edu understanding and knowledge gained)
Safety	Harm due to programme intervention	Records of complications within the programme	Number and type of incidences which led to
Efficiency	Regional or waiting-related underuse	Optimal use of service, i.e. availability and accessibility of courses (e.g. region, waiting lists)	Regional distribution of courses Number of days/weeks from application until
<b>Secondary outcomes – clinical/patient outcomes</b>			
Clinical/patient outcomes	Improvement of OA-related symptoms, function and quality of life	Effects of programmes, i.e. impact on pain, physical function and quality of life	- Percentage of pain reduction among all par - Percentage of improvement in physical fun - Percentage of improvement in quality of life

PTs – Physiotherapists, MDs – Medical Doctors, OA – Osteoarthritis

## Discussion

The protocol describes the proposed measures, data sources and strategies to evaluate the impact of the GLA:D® Switzerland OA programme. The implementation strategy at the different

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levels aims to improve acceptability among the key stakeholders and, therefore, enhance adoption, penetration and, ideally, long-term sustainability. However, the implementation of a new programme is not a linear process and needs continuous evaluation. The predefined implementation outcomes will help to identify barriers and facilitators systematically, and to explain the reasons for the success or failure of specific elements of the implementation strategy. The results will feed into the planning of further implementation activities. Furthermore, they facilitate the determination of the factors that require more attention for the systematic application of the GLA:D® Switzerland OA programme.

Clinical observations confirm that there is usually a wait-and-see strategy in the conservative management of knee OA or patients are simply referred to physiotherapy, which often focusses on hands-on techniques. Therefore, the systematic implementation of the GLA:D® Switzerland OA programme was initiated to improve the conservative management of knee OA by enhancing first-line intervention exercise and education. GLA:D® is a so-called best-practice exercise and education programme that has already been successfully implemented in other countries. Quality improvements have already been made and lessons have been learned from prior implementations in other countries (6). This has helped in designing the implementation in Switzerland.

The original GLA:D® programme did not focus on weight reduction, but its inclusion could be of importance in the Swiss context, since some 42% and 11% of Swiss adults are considered overweight and obese, respectively, in the year 2020 (28). Weight reduction is also one of the first-line intervention recommendations in conservative knee OA management, since overweight and obesity are major risk factors for developing knee OA (1-5).

It is seen as a significant strength that the evaluation of the implementation of the GLA:D® Switzerland OA programme is based on the use of frameworks and implementation theories. These theories help to structure and guide the planning, execution and evaluation of an implementation project (23). A structured evaluation will be useful in determining the need for and the types of further implementation activities (20,23). Furthermore, the systematic and

structured evaluation process, using the IRLM, can be transferred to the development or evaluation of implementation strategies of other projects in chronic care management. The inclusion of the major stakeholders, such as health care providers (PTs, referring doctors), their scientific and professional societies, as well as patients in the implementation process is necessary to understanding the reasons, including facilitators and barriers for adoption, penetration and sustainability. The mixed-methods approach helps to cover many facets for understanding the context and implementation barriers or facilitators.

Evaluation studies have often described 'lessons learned', meaning barriers or facilitators that have emerged during an implementation process (6). To date, no gold standard exists for the evaluation of implementation strategies and no clear-cut decision can be made on whether an implementation was successful (20). Thus, this evaluation of the implementation impact will be the result of combining numerous outcomes with pragmatic explanations of its success or failure in a certain context (20). It is yet unclear how many survey participants or interview partners will be recruited, however, in contrast to previously defined sample sizes in clinical trials, in implementation studies the focus is on selecting representative samples. Therefore, assessing results in heterogeneous, unselected population and real-life clinical setting are important considerations when analysing the representativeness of the results (29).

The results of this evaluation will assist in determining how the programme contributes to the overall goal of improving the conservative non-pharmacological management of patients with knee OA in Switzerland. Moreover, the acquired knowledge and lessons learned regarding implementation in this study might also be transferred to other implementation projects in the field of chronic care management.

### **Ethical and dissemination**

The data registry containing data of patients participating in the GLA:D® Switzerland OA programme is declared as a quality project by the Zurich ethics committee and does not fall within the scope of the Swiss Human Research Act (BASEC-Nr. Req-2019-00274). However, all participants involved in the evaluation, will be asked to give informed written consent.

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**Authors' contributions**

LE and KN conceptualized and designed the study protocol and drafted the manuscript. MB, OG, IN and AKR contributed to subsequent drafts and all authors revised and approved the manuscript for publication.

**Competing interests**

KN is head of research GLA:D® Switzerland OA.  
The symbol ® in GLA:D® stands for 'quality-controlled programme', with no commercial interests.

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**Word count**

3603

**Figures**

*Figure 1: Implementation Research Logic Model (IRLM) by Smith et al. (2020) (23)*

*Figure 2: Implementation Research Logic Model (IRLM) used for the implementation of GLA:D® Switzerland OA*

EBI – Evidence-Based Intervention; PTs – Physiotherapists; MDs – Medical Doctor, IG GLA:D® - Interest Group GLA:D® Switzerland; NCD – Non-Communicable Disease; WHO – World Health Organisation; SLR- Swiss League against Rheumatism; OA – Osteoarthritis

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Figure 1: Implementation Research Logic Model (IRLM) by Smith et al. (2020) (23)

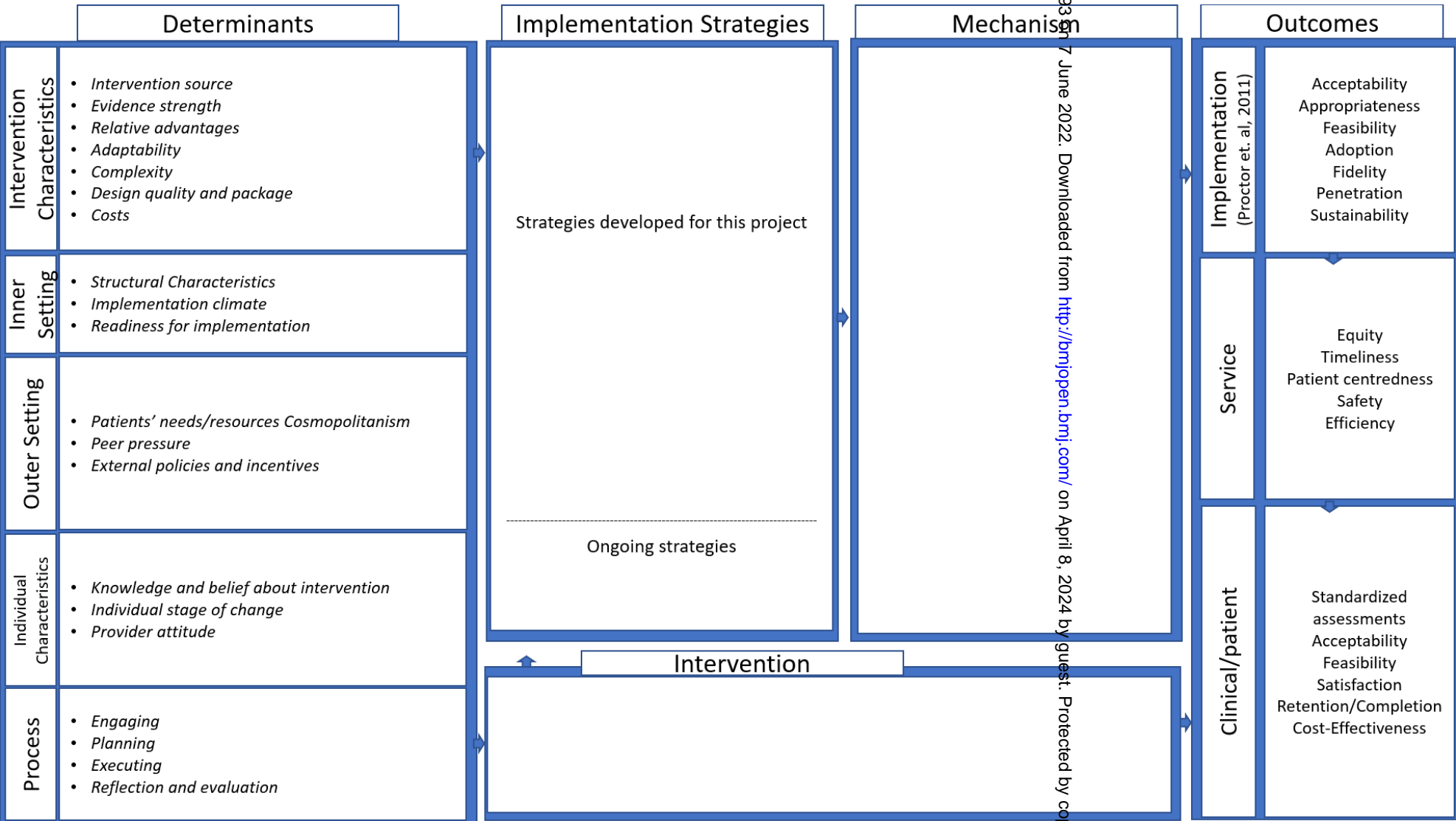
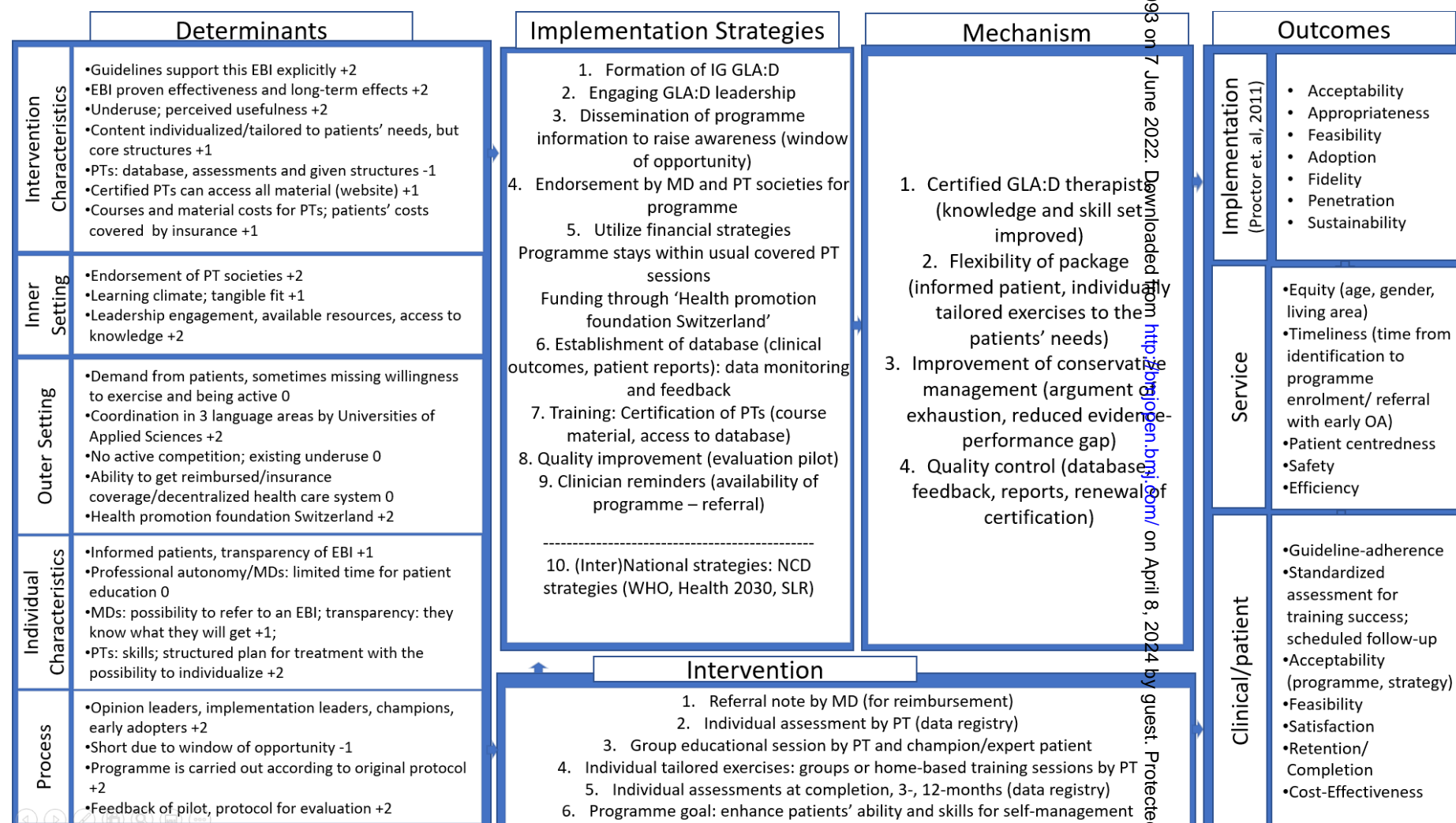


Figure 2: Implementation Research Logic Model (IRLM) used for the implementation of GLA:D® Switzerland OA



EBI – Evidence-Based Intervention; PTs – Physiotherapists; MDs – Medical Doctor, IG GLA:D® - Interest Group GLA:D® Switzerland; NCD – Non-Communicable Disease; WHO – World Health Organisation; SLR- Swiss League against Rheumatism; OA – Osteoarthritis

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Supplement I: Matrix of the influences on the implementation outcomes

	Acceptability	Appropriateness	Feasibility	Adoption	Fidelity	Penetration	Sustainability
<b>Determinants</b>							
Guidelines support this EBI explicitly	X	X					
EBI proven effectiveness and long-term effect	X	X					
Underuse; perceived usefulness	X	X					
Content individualized/tailored to patients' needs, but core structure	X	X	X				
PTs: database, assessments and given structures	X	X	X				
Certified PTs can access all material (website)	X	X	X				
Courses and material costs for PTs; patients' costs covered by insurance	X	X	X				
Endorsement of PT societies	X						
Learning climate, tangible fit	X						
Leadership engagement, available resources, access to knowledge	X						
Demand from patients, sometimes missing willingness to exercise and being active	X	X					
Coordination in 3 language areas by Universities of Applied Sciences	X						
Informed patients, transparency of EBI	X	X					
Professional autonomy/MDs: limited time for patient education	X						
MDs: possibility to refer to an EBI; transparency: they know what they will get	X	X					
PTs: skills; structured plan for treatment with the possibility to individualize	X	x					
<b>Implementation Strategies</b>							
Formation of IG GLA:D							
Dissemination of programme information to raise awareness (window of opportunity)	X	x		X		X	
Endorsement by MD and PT societies for programme	X	x		X			X
Utilize financial strategies	X	x		X		X	X

Programme stays within usual covered PT sessions							
Establishment of database (clinical outcomes, patient reports): data monitoring and feedback							X
Training: Certification of PTs (course material, access to database)	X			X		X	
Quality improvement (evaluation first courses)	X			X		X	
Clinician reminders (availability of programme – referral)	X			X			X
(Inter)National strategies: NCD strategies (WHO, Health 2030, SLR)	X			X		X	X
<b>Mechanism</b>	x			x		X	



Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. BMJ 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. BMJ Open 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			“Implementation strategy” refers to how the intervention was implemented		“Intervention” refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	1	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	2	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	3	3/4	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	4	3/4	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).		The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	5	5	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	6	5	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	7	3/4/7	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	8	10	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.		The population targeted by the intervention and any eligibility criteria.
Description	9	7/8	A description of the implementation strategy		A description of the intervention
Sub-groups	10	11	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	11	10	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets		Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	12	10	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	13	na	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy		Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	14	na	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	15	11/12	Methods of analysis (with reasons for that choice)		
Sub-group analyses	16	11/12	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

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Results					
Characteristics	17	na	Proportion recruited and characteristics of the recipient population for the implementation strategy		Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	18	na	Primary and other outcome(s) of the implementation strategy		Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	19	na	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	20	na	Resource use, costs, economic outcomes and analysis for the implementation strategy		Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	21	na	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/adaptation	22	na	Fidelity to implementation strategy as planned and adaptation to suit context and preferences		Fidelity to delivering the core components of intervention (where measured)
Contextual changes	23	na	Contextual changes (if any) which may have affected outcomes		
Harms	24	na	All important harms or unintended effects in each group		
Discussion					
Structured discussion	25	13/14	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	26	14	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)		Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	27	17	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

# BMJ Open

## Evaluation of the strategy for implementing the GLA:D® programme in Switzerland - protocol for an implementation-effectiveness hybrid type 3 design study with a mixed-methods approach

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**Evaluation of the strategy for implementing the GLA:D® programme in Switzerland - protocol for an implementation-effectiveness hybrid type 3 design study with a mixed-methods approach**

**Lea Ettlin<sup>1,2\*</sup>, Marina Bruderer- Hofstetter<sup>1</sup>, Olivier Gaugler<sup>1</sup>, Irina Nast<sup>1</sup>, Anne-Kathrin Rausch Osthoff<sup>1</sup>, Karin Niedermann<sup>1</sup>**

<sup>1</sup> Institute of Physiotherapy, School of Health Professions, Zurich University of Applied Sciences, Winterthur, Switzerland  
<sup>2</sup> Department of Health Sciences and Health Policy, University of Lucerne, Lucerne, Switzerland

**\* Correspondence:**  
Lea Ettlin  
xetl@zhaw.ch

**Keywords (3-10):** Exercise and education programmes; Implementation; Knee Osteoarthritis; IRLM; Evaluation; Study protocol.

## Abstract

**Introduction:** International guidelines recommend the use of exercise, education and weight reduction, when appropriate, as first line treatment for the conservative management of knee osteoarthritis (OA). These guidelines have not been applied systematically in Switzerland, resulting in an evidence-performance gap. After an analysis of available programmes, the GLA:D® programme was determined as the most applicable exercise and education programme for its implementation in Switzerland. The implementation of GLA:D® Switzerland OA was initiated to encourage the wider implementation of the clinical guideline recommendations and to improve conservative management of knee OA. The aim of this study protocol is to describe the evaluation of the implementation strategy and its impact on implementation, service and clinical outcomes; as well as to identify contributing barriers and facilitators.

**Methods and analysis:** The Implementation Research Logic Model (IRLM) will be used to evaluate the strategy and analyse its impact on the implementation outcomes by means of a mixed methods approach. This protocol outlines the proposed measures, data sources and strategies for the evaluation. Predefined implementation outcomes will help to identify the implementation impact and analyse barriers and facilitators systematically. The study population will be the health care professionals who are involved in the conservative management of knee OA in Switzerland, i.e., physiotherapists and medical doctors, and their patients.

### **Ethics and dissemination:**

The use of the registry data containing data of patients participating in the GLA:D® Switzerland OA programme does not fall within the scope of the Swiss Human Research Act (BASEC-Nr. Req-2019-00274). However, all participants involved in the evaluation, will be asked to give informed written consent and all measures are taken to protect data and privacy of participants. Research findings will be submitted to journals relevant for the topic.

**Trial registration:** not applicable.

**Strengths and limitations**

- The structured evaluation by the use of frameworks and implementation theories helps to determine the need for and the types of further implementation activities and can also be transferred to other project in chronic care management
- Participants/Patients are involved in the evaluation process to determine if the implementation is meeting their needs
- The mixed-methods approach helps to cover many facets for understanding the context and implementation barriers or facilitators
- There is no gold standard for the evaluation of implementation strategies and no clear-cut decision can be made on whether an implementation was successful
- The recruitment rate is yet unclear for survey participants or interview partners, however, in implementation studies the focus is not on sample size, but on selecting representative samples, i.e., assessing results in heterogeneous, unselected population and real-life clinical setting

**Introduction**

**Exercise and education for knee osteoarthritis**

Knee osteoarthritis (OA) represents a major burden both for the patient and the health care system (1,2). The international clinical guidelines of Osteoarthritis Research Society International (OARSI), European Alliance of Associations for Rheumatology (EULAR) and American College of Rheumatology (ACR) recommend exercise, education and, when appropriate, weight reduction as the first line intervention in the conservative management of knee OA (3–5). These interventions aim to improve knee OA-related symptoms and enhancing patients’ self-management (6). Exercise and education programmes for knee OA that translate the guideline recommendations into clinical practice have been shown to be feasible and effective (6–14). Some are endorsed by OARSI, e.g., ‘Better management of Patients with

OsteoArthritis' (BOA), 'OsteoArthritis Chronic Care Program' (OACCP) or 'Good Life with osteoArthritis Denmark' (GLA:D®) (6,10,11). A prior analysis of the OARSI-approved programmes resulted in the GLA:D® programme as the most applicable exercise and education programme for implementation in Switzerland, since it had the highest congruency of settings and the highest chance for successful implementation (15).

### **Implementation of an exercise and education programme in Switzerland**

Knee OA is the most treated diagnosis in Swiss hospitals but, since patient data in an outpatient setting are not systematically collected, the prevalence and incidence of knee OA remain unclear and are mainly based on data from the inpatient setting (16). However, even though data from the outpatient setting is missing, clinical observations and the high number of surgeries indicated that the prevalence of knee OA is high. Therefore, a survey among medical specialists, working in primary care, was performed to gain insight on the conservative management of knee OA in the outpatient setting of Switzerland (17). The results showed that the estimated referral rate to exercise was of some 54% only and, thus, indicated an evidence-performance gap in the conservative management of knee OA (17). The study demonstrated that guideline recommendations were not applied systematically in clinical practice and there was a need to implement a structured exercise and education programme to close this evidence-performance gap. Furthermore, there is missing transparency in the management of knee OA assuming that patients with knee OA are usually treated with hands-on techniques in physiotherapy. This assumption that PTs seem not to manage knee OA patients according to the guidelines, has also been confirmed in many other countries (18,19,20) An exercise and education programme might help to systematically translate the guideline recommendations into practice.

As a result, a network of physiotherapy experts in OA management founded the interest group 'IG GLA:D® Switzerland' in 2019 with the aim of implementing the GLA:D® programme in Switzerland. The IG consists of six research physiotherapists from three Universities of Applied Sciences in the German, French and Italian language areas of Switzerland, two clinical

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practitioners representing two specialist physiotherapy societies, and one patient representative of the Swiss League Against Rheumatism (SLAR). Programmes like GLA:D® apply standardized assessments and progress reports which can help to ascertain if the interventions help improving the participants' symptoms. GLA:D® is a treatment concept for OA, developed by the university of Southern Denmark, and is being implemented internationally. Therefore, its adaptability to personal or nation-specific needs is limited to guarantee, that GLA:D® is the same to patients and other stakeholders wherever it is provided (11). However, the implementation of a new programme in a health care system is complex and involves multiple levels in the health care system and health care delivery (21). The impact of the implementation can be evaluated through the measurement of implementation outcomes, combined with the effects of the programme and the contextual factors that influence the outcomes (22).

**Aims and objectives**

To understand whether the GLA:D® Switzerland OA programme has been implemented appropriately, it is important to evaluate the impact of the implementation strategy itself and not only to focus on the programme's effects, i.e., participants' clinical outcomes (22–24). The impact of the implementation is conceptualized by various implementation outcomes (e.g. acceptability, appropriateness, feasibility, adoption, fidelity, penetration and sustainability) including the effects of the programme (23). Therefore, the overall aim of this study is to describe the implementation strategy and the process how to evaluate its impact.

The specific aims of this evaluation are:

- 1. To evaluate the impact of implementation strategy of GLA:D® Switzerland OA based on the implementation outcomes and analyse the influencing factors (barriers and facilitators).
- 2. To analyse the effect of the implementation strategy on the provision of health service and clinical outcomes.

**Methods and analysis**

## Study design

An implementation-effectiveness hybrid type 3 design with a mixed-methods approach will be employed (25).

The reporting of this study protocol follows the 'Standards for Reporting Implementation studies' (StaRI) statement.

## Evaluation framework

This evaluation is guided by the Implementation Research Logic Model (IRLM), developed by Smith, Li and Rafferty (2020) (26). The IRLM is based on the theory that an implementation strategy is dependent on specific implementation determinants, i.e., context-specific barriers and facilitators, and works through a specific mechanism of action to change the behaviours of the involved people within the context.

The IRLM format chosen for this evaluation comprises five foundational elements (see Fig. 1):

1. *Determinants* – the determinants used in the IRLM are based on the Consolidated Framework for Implementation Research (CFIR) and provide information on the potential barriers and facilitators in the five different IRLM domains, i.e., intervention characteristics, inner setting, outer setting, individual characteristics, and process. For each determinant, valence is noted to indicate the possible impact of the determinant on the implementation from +2 (strong positive = facilitator) to -2 (strong negative = barrier).
2. *Implementation Strategies* – the implementation strategies occur on multiple levels to support adoption into usual care. These strategies can be developed specifically for the implementation project, but can also be supported by ongoing strategies.
3. *Mechanism* - the mechanism of action, which can also be part of 'implementation strategy', has an influence on most of the implementation outcomes. It describes the process through which the strategy operates to affect the desired outcomes.
4. *Intervention* – the intervention elucidates the functionality of the programme that has been implemented.

5. *Outcomes* - the outcomes in the IRLM are subdivided into implementation, service, and clinical/patient outcomes. The implementation outcomes described by Proctor et al. (2011) include acceptability, appropriateness, feasibility, adoption, fidelity, penetration, and sustainability (23). The leading indicators for analysing implementation success, i.e., acceptability, appropriateness, and feasibility, are often evaluated during the implementation process to manage the strategies and predict future trends for the other outcomes (23). The outcomes are interdependent on each other, and their results are influenced by the different ‘Determinants’, ‘Implementation strategies’ and ‘Mechanism’ (25,26,27). The influences on the implementation outcomes acceptability, appropriateness, feasibility, adoption, fidelity, penetration, and sustainability are outlined with in supplement material 1.

Figure 1 shows the IRLM format with the five foundational elements and Figure 2 the IRLM applied for this project. The use of the IRLM elements in this implementation project are explained in detail in the subsequent sections.

➔ *Figure 1*

➔ *Figure 2*

*IRLM - Determinants*

The determinants of the implementation of exercise and education as first-line intervention are described in the five different domains. These determinants that act potentially as facilitators or barriers as indicated by valence, were examined in the early stage of the implementation process. This was firstly accomplished through surveys of medical doctors (specialists in general primary care, rheumatology, and orthopaedics) and of the physiotherapists (PTs) who attended the first GLA:D® certification courses. Additionally, contextual factors were analysed in a policy brief and a stakeholder dialogue (17,28,29).

*IRLM - Implementation strategies*

The guideline-based GLA:D® programme involves PTs and referring medical doctors working in a structured treatment pathway and applying their knowledge and skills within their

professional roles. The establishment of a database for GLA:D®-related data allows standardised reporting of the individual participant's clinical outcomes and the monitoring of the overall quality of the programme.

For the implementation of the GLA:D® Switzerland OA programme there are several strategies being used. Representatives of three medical doctor and two physiotherapy scientific societies, of a patient organisation and an expert from physiotherapy research, are included as key stakeholders in the implementation process and their attitudes and points of view on a programme are assessed and considered carefully. To increase awareness and acceptance, the programme is actively disseminated and promoted through various means and venues (e.g., information flyers and scientific presentations for health professionals; information flyers and mass media reports for the public), as well as through network building. Medical specialists and PTs are the main target groups of the strategy. Medical specialists can refer the patients to the programme and therefore, have to be aware of and accept the programme. PTs, are also an important target group, since, after successful participation in the certification courses, they are the programme providers. This topic is described in more detail in 'mechanism of action'. The GLA:D® Switzerland OA programme is embedded within the reimbursement system for physiotherapy treatment, i.e., reimbursement of physiotherapy is covered by basic health insurance if referred by a medical doctor. Moreover, this project fits well to existing international and national ongoing strategies, which is beneficial to its implementation and funding: A) The implementation goals of this project are commensurate with the World Health Organisation (WHO) strategy 'Health 2020 and 2030' for the prevention and treatment of noncommunicable diseases (NCDs) (27). B) A national strategy for musculoskeletal diseases also exists, including one for OA management (30).

### *IRLM - Mechanism*

The mechanism of action for GLA:D® Switzerland consists of three components: 1) certification courses for PTs; 2) the GLA:D® Switzerland OA programme for patients; and 3) data registry for quality monitoring.

*Certification course:* The attendance of the 2-day certification course allows Swiss PTs to offer the GLA:D® programme within their institutions. The course advances knowledge in the fields of OA and evidence-based treatment. It enables the ability to offer the specific GLA:D® educational and exercise sessions, perform the clinical tests and use the data registry. After successful completion of the certification course, PTs can implement GLA:D® Switzerland OA within their setting. The certificate is valid for 3 years and must be renewed thereafter.

*GLA:D® Switzerland OA programme:* The GLA:D® Switzerland OA programme includes: 1) an initial examination (e.g., medical history, personal factors, participant's characteristics), clinical tests, and data registry; 2) education sessions, with the goal that the participants understand the diagnosis and the management of OA; and 3) an evidence-based exercise programme in which PTs individually tailor the standardised exercises to the participants' needs.

*Data registry:* All demographic and clinical patient data are registered in a national database. The registry also includes participants' individual clinical outcomes and allows an evaluation of the quality of the treatment, e.g., standardised feedback or reports to the referring doctor, and the monitoring of the overall quality of the programme.

*IRLM - Intervention*

People with knee pain or diagnosed knee OA can participate in the programme. The programme consists of 1) three individual sessions for assessments at baseline and information/instruction of the standardised and individually tailored exercises; 2) two patient education sessions; and 3) twelve PT-supervised group exercise sessions where the exercises are continuously and individually adapted with regard to dose and difficulty. The baseline assessments are repeated during another individual session on completion of the programme. The predefined outcomes are assessed at the 12-month follow-up. The programme's goal is to enhance the patient's ability and skills to self-manage their health condition. Referring doctors receive a short, standardised report informing them of the intervention effect after completion of the programme.

*IRLM - Outcomes*

*Implementation outcomes:* Seven implementation outcomes will be used to analyse the success of the implementation strategy and to determine which factors influenced its success or failure (23). Both the implementation strategy and the mechanism of action can influence the implementation outcomes (26). The combination of all outcomes - implementation, service and clinical/patient - will indicate the implementation success of GLA:D® Switzerland OA.

*Service outcomes:* The annual report of GLA:D® Switzerland OA provides information on the service outcomes, such as equity or patient centredness (e.g., satisfaction). However, these outcomes will be analysed in more depth to determine whether GLA:D® Switzerland OA offers a good clinical pathway.

*Clinical/patient outcomes:* The programme's impact on the individual participant is evaluated systematically and a summary of the outcomes for all participants is reported annually.

### **Evaluation implementation strategy**

The primary and secondary evaluation outcomes relating to implementation, service and clinical/patient outcomes are described in Table 1.

#### *Primary outcome:*

The primary outcome will be the evaluation of the implementation impact of GLA:D® Switzerland OA by analysing various factors (acceptability, appropriateness, feasibility, adoption, fidelity, penetration and sustainability) (23). The extent of adoption and penetration is influenced by acceptability, appropriateness, feasibility and fidelity. The analysis will allow the prediction of the sustainability of the programme application and the drawing of conclusions on the implementation success.

#### *Secondary outcomes:*

1) Service outcomes will be analysed to determine whether GLA:D® Switzerland OA offers a good clinical pathway. The service outcomes are largely linked to barriers and facilitators on the level of 'intervention characteristics', but also to implementation strategies, e.g., utilisation of financial strategies, or reminding clinicians have an impact on service outcomes.

2) Clinical/patient outcomes are monitored systematically by the IG GLA:D® and reported annually on the website of GLA:D® Switzerland ([www.gladswitzerland.ch](http://www.gladswitzerland.ch)). This will help to make sure that the programme's effects are not compromised through the process of implementation (25).

**Study population**

The study population for this evaluation will consist of GLA:D®-certified and 'usual care' PTs, referring and non-referring primary care medical doctors, and GLA:D® participants. An analysis will be made of the proportional distribution of the representatives of their group, regarding their characteristics (e.g. age, gender, type of outpatient setting) in the three Swiss language areas, i.e., German, French and Italian

**Patient and Public Involvement**

Patients or, in this case, GLA:D® participants, are actively involved in the implementation process and evaluation. In the stakeholder dialogue and other implementation activities the patients were represented by the SLAR. However, the implementation evaluation will include a patient survey to assess the implementation outcomes on the patient level and to see if the programme meets the patients' needs or if there are possible barriers for adoption of the programme.

**Data collection and analysis**

The evaluation will involve several data sources. Primary data sources are: 1) the data registry of GLA:D® participants, i.e. patients and GLA:D®-certified PTs; 2) data from surveys (Likert scales and open questions) with representative samples, i.e. as far as possible all who participate in / refer to / provide the GLA:D® programme during a certain time period. Furthermore, a representative number of patients, PTs, medical specialists, depending on the number of people supporting GLAD, who do not support the programme; and 3) qualitative data from in-depth interviews. For the interviews, data saturation will indicate when there are enough participants. Patient data in the registry will be assigned a study ID number and will be used anonymised for the evaluation. Data from the surveys and the qualitative data will also

be anonymised through an assigned study ID number and stored on a local server. All survey participants and interview partners will be asked for permission to use their anonymised data through an informed consent. They will be apprised that participation is voluntary.

For assessing implementation success, surveys will be developed to empirically evaluate acceptability, appropriateness and feasibility in the various stakeholder groups, i.e., PTs, patients, medical doctors or institutions and clinics. For the evaluation of adoption, three implementation streams will be assessed, i.e., the number of: 1) medical doctors referring patients with OA to GLA:D® Switzerland OA; 2) PTs and organisations offering GLA:D® Switzerland OA; and 3) patients participating in the GLA:D® Switzerland OA programmes. A stratification question at the beginning of the surveys will be posed to ascertain whether the survey participant is still actively involved in GLA:D® Switzerland OA. The associated outcomes of adoption and penetration will both be analysed using data from the registry and national statistical data. Fidelity will be tested through observation, based on predefined criteria on a standardised checklist. The outcome of sustainability is determined by the other implementation outcomes over time and, consequently, will be analysed at a later stage (minimum 4 years).

The surveys' responses and data from the registry will be quantitatively analysed and reported as frequencies, means and standard deviations. Subgroup analysis on participant characteristics (e.g., type of practice, age, profession, language area) will be performed to detect possible barriers to adoption or penetration. The characteristics of the GLA:D®-participating PTs, patients and medical doctors will be documented and compared for representativeness. Depending on data availability, the representativeness of the participating PTs, patients and medical doctors will be assessed through comparison with their non-participating associates.

The implementation outcomes will be evaluated further through (qualitative) in-depth analyses with selected PTs, patients, and medical doctors, where appropriate. The qualitative data will be anonymised, transcribed, and digitally recorded for subsequent analysis. These data can

be used to explain the results of the surveys and the data registry, or for further exploration of barriers and facilitators. Moreover, they can also be employed to analyse service outcomes.

Secondary outcomes

The service outcome of equity will be studied by analysing patient characteristics from the registry (i.e., age, gender, and region or language areas) and appropriate in-depth interviews. The patient survey will include questions on timeliness, patients' centredness, safety and efficiency. PTs will also be approached with a question in the survey on the complications of patient safety during their courses. The outcome of fidelity and appropriateness will provide information on patients' centredness and safety. These results may be further deepened by qualitative measures.

Clinical/patient outcomes are assessed for each patient participating in the programme. Pain, use of painkillers, functional ability, quality of life and satisfaction are measured within the programme. These outcomes are available from the data registry and are regularly analysed in the GLA:D®-programme annual report. Analysis of the annual reports will provide further explanations of the implementation outcomes.

Table 1: Evaluation of primary and secondary outcomes - implementation, service, and clinical/patient-related outcomes

Outcomes	Operationalisation	Indicator	Assessment
Acceptability	Perception that the programme offers a good pathway and acceptance to apply systematically as first line intervention	<ul style="list-style-type: none"><li>- Willingness of PTs, patients and MDs to be involved in the programme</li><li>- Acceptance of the systematic application of programme as first-line intervention in conservative management by PTs and MDs.</li></ul>	Degree of acceptability of: <ul style="list-style-type: none"><li>- content and delivery of GLA:D® Switzerland</li><li>- certification courses (PTs)</li><li>- process, including delivery organisation and complexity of assessments and data registry</li><li>- referring process and reporting (MDs)</li></ul>
Appropriateness	Perceived fit (in the setting, with the current practice) or relevance of the programme for patients with knee OA.	<ul style="list-style-type: none"><li>- Perceived fit of programme to provide good management for patients with knee OA</li><li>- Perceived relevance of programme</li><li>- Compatibility of programme with the setting and its usual care.</li></ul>	Degree of perceived fit of: <ul style="list-style-type: none"><li>- content and outcome of GLA:D® Switzerland</li><li>- certification courses (PTs)</li><li>- process, including delivery organisation and usefulness of a data registry in order to increase</li></ul> Degree of compatibility of: <ul style="list-style-type: none"><li>- certification courses</li><li>- programme</li><li>- administrative work with the current practice (PTs)</li></ul> Degree to which GLA:D® Switzerland OA meets guidelines recommendations (PTs, patients, MDs)
Feasibility	Extent to which programme can be carried out easily and successfully in daily routine	<ul style="list-style-type: none"><li>- Extent to which programme can be carried out easily in daily routine, e.g. complexity, adaptability, resource availability by PTs and patients</li><li>- Extent to which programme can be used successfully in the physiotherapeutic context</li></ul>	Degree of feasibility of GLA:D® Switzerland OA: <ul style="list-style-type: none"><li>- content, e.g. complexity and adaptability (PTs)</li><li>- delivery, e.g. sufficiency of training and resources (patients)</li><li>- performance for daily routine, e.g. sufficiency of resources (patients)</li><li>- referral to GLA:D® Switzerland OA (MDs)</li></ul>

		- Extent of the sufficiency of training / certification courses for the readiness to provide the programme regularly by PTs - Extent to which referral to the programme is feasible for MDs	
Adoption	Application of the programme in the outpatient setting (PT practices, ambulatory of hospitals, clinics and nursing homes)	Absolute number, proportion, and representativeness of: - PTs in outpatient setting (PT practices, ambulatory of hospitals, clinics and nursing homes) who were approached compared to the ones who are offering the programme - programme participants (increase over time, regional differences, dropouts) - referrals (increase over time, regional differences, characteristics of medical doctors, referral pattern over time) - clinics, hospitals, institutions, practices offering the programme (increase over time, regional differences)	Total number of PTs, patients, MDs, and inst involved in GLA:D® Switzerland OA, Proport Analysis of adherence to programme until fo Analysis of characteristics, e.g. how many di pattern over time (MDs) Comparison of characteristics between partic institutions, clinics, practices, <i>depending on</i>  Additional: Reasons for withdrawal – analys
Fidelity	Implementation of programme according to original protocol.	Degree to which programme has been implemented in participating PT practices as intended	Fidelity evaluation on 5 dimensions: - adherence to programme protocol - programme component differentiation - participant responsiveness or involvement - dose or amount of programme delivered - quality of programme  Additional analysis of barriers and facilitators
Penetration	Institutionalisation or integration of the programme within the field of physiotherapy.	Absolute number of institutionalisations or integration of programme within the field of physiotherapy, institutions, clinics or practices. Proportion and representativeness of PTs or MDs willing to be involved in the programme.	Number of GLA:D®-certified PTs delivering G by the total number of PTs in Switzerland  Number of MDs referring to GLAD® OA Switz number of MDs (GPs, rheumatologists and d Ability to estimate and identify targeted patie including facilitators and barriers  Number of institutions, clinics or practices off total number of institutions, clinics or practice hip OA.
Sustainability	Maintenance of programme in the field of physiotherapy as usual care.	Diffusion of the programme in the field of physiotherapy and continuity of courses. Referral by MDs to programme as usual care for people with knee OA Integration of the programme into the organisational culture through policies and practices	- Systematic offers of GLAD® OA Switzerland region, number of courses, continuity (PTs, d - Systematic referral to GLAD® OA Switzerland number of courses, continuity (MDs). - Exploration and evaluation of possible barr organisations) - Analysis of internal culture (organisation) - Number of patients undergoing surgery with GLAD® OA Switzerland versus usual care
<b>Secondary outcomes - service outcomes</b>			
Equity	Avoiding unconscious bias	Prevalence of patients participating in the programme based on age, gender, region. Reasons as to why eligible patients are not referred.	- Percentage of GLAD® OA Switzerland part gender, region (subgroup analysis) - Analysis of reasons, characteristics of eligib if possible
Timeliness	Reduced waiting time and avoidance of (harmful) delays	Time from identification (knee OA or knee pain) to programme	Number of months from identification of OA t Switzerland
Patients centredness	Respectful care and responsiveness to patients' need and values	Patients' willingness to participate in programme and their satisfaction with content	Degree of satisfaction on: - content of GLA:D® Switzerland OA, i.e. edu understanding and knowledge gained)
Safety	Harm due to programme intervention	Records of complications within the programme	Number and type of incidences which led to
Efficiency	Regional or waiting-related underuse	Optimal use of service, i.e. availability and accessibility of courses (e.g. region, waiting lists)	Regional distribution of courses Number of days/weeks from application until
<b>Secondary outcomes – clinical/patient outcomes</b>			
Clinical/patient outcomes	Improvement of OA-related symptoms, function and quality of life	Effects of programmes, i.e. impact on pain, physical function and quality of life	- Percentage of pain reduction among all par - Percentage of improvement in physical fun - Percentage of improvement in quality of life

PTs – Physiotherapists, MDs – Medical Doctors, OA – Osteoarthritis

## Discussion

The protocol describes the proposed measures, data sources and strategies to evaluate the impact of the GLA:D® Switzerland OA programme. The implementation strategy at the different

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levels aims to improve acceptability among the key stakeholders and, therefore, enhance adoption, penetration and, ideally, long-term sustainability. However, the implementation of a new programme is not a linear process and needs continuous evaluation. The predefined implementation outcomes will help to identify barriers and facilitators systematically, and to explain the reasons for the success or failure of specific elements of the implementation strategy. The results will feed into the planning of further implementation activities. Furthermore, they facilitate the determination of the factors that require more attention for the systematic application of the GLA:D® Switzerland OA programme.

Clinical observations confirm that there is usually a wait-and-see strategy in the conservative management of knee OA or patients are simply referred to physiotherapy, which often focusses on hands-on techniques. Therefore, the systematic implementation of the GLA:D® Switzerland OA programme was initiated to improve the conservative management of knee OA by enhancing first-line intervention exercise and education. GLA:D® is a so-called best-practice exercise and education programme that has already been successfully implemented in other countries. Quality improvements have already been made and lessons have been learned from prior implementations in other countries (6). This has helped in designing the implementation in Switzerland.

The original GLA:D® programme did not focus on weight reduction, but its inclusion could be of importance in the Swiss context, since some 42% and 11% of Swiss adults are considered overweight and obese, respectively, in the year 2020 (31). Weight reduction is also one of the first-line intervention recommendations in conservative knee OA management, since overweight and obesity are major risk factors for developing knee OA (1-5).

It is seen as a significant strength that the evaluation of the implementation of the GLA:D® Switzerland OA programme is based on the use of frameworks and implementation theories. These theories help to structure and guide the planning, execution and evaluation of an implementation project (26). A structured evaluation will be useful in determining the need for and the types of further implementation activities (23,26). Furthermore, the systematic and

structured evaluation process, using the IRLM, can be transferred to the development or evaluation of implementation strategies of other projects in chronic care management. The inclusion of the major stakeholders, such as health care providers (PTs, referring doctors), their scientific and professional societies, as well as patients in the implementation process is necessary to understanding the reasons, including facilitators and barriers for adoption, penetration and sustainability. The mixed-methods approach helps to cover many facets for understanding the context and implementation barriers or facilitators.

Evaluation studies have often described 'lessons learned', meaning barriers or facilitators that have emerged during an implementation process (6). To date, no gold standard exists for the evaluation of implementation strategies and no clear-cut decision can be made on whether an implementation was successful (23). Thus, this evaluation of the implementation impact will be the result of combining numerous outcomes with pragmatic explanations of its success or failure in a certain context (23). It is yet unclear how many survey participants or interview partners will be recruited, however, in contrast to previously defined sample sizes in clinical trials, in implementation studies the focus is on selecting representative samples. Therefore, assessing results in heterogeneous, unselected population and real-life clinical setting are important considerations when analysing the representativeness of the results (32).

This study protocol for the evaluation of an implementation strategy will help to monitor systematically the impact of the implementation of GLA:D® Switzerland OA and to continuously identify and address its barriers and facilitators. The results of the evaluation will assist in determining how the programme contributes to the overall goal of improving the conservative non-pharmacological management of patients with knee OA in Switzerland. Moreover, the acquired knowledge and lessons learned regarding implementation in this study might also be transferred to other implementation projects in the field of chronic care management.

## **Ethics and dissemination**

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The data registry containing data of patients participating in the GLA:D® Switzerland OA programme is declared as a quality improvement project by the Zurich ethics committee and does not fall within the scope of the Swiss Human Research Act (BASEC-Nr. Req-2019-00274). However, all participants involved in the evaluation, will be asked to give informed written consent.

PTs can only see their own programme participants in the system. All data will be treated according to the privacy regulations applicable for Switzerland. Collected data will be secured against unauthorised access and will be stored and secured by the University of Applied Sciences Zurich. No data that can identify a participant will be processed for this evaluation to protect and respect the privacy of all participants. The main research team including the principal investigator have access to all anonymised data. Manuscripts with research findings will be submitted to relevant peer-reviewed journals.

**Authors’ contributions**

LE and KN conceptualized and designed the study protocol and drafted the manuscript. MB, OG, IN and AKR contributed to subsequent drafts and all authors revised and approved the manuscript for publication.

**Competing interests**

KN is head of research GLA:D® Switzerland OA.  
The symbol ® in GLA:D® stands for ‘quality-controlled programme’, with no commercial interests.

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## Word count

3801

## Figures

*Figure 1: Implementation Research Logic Model (IRLM) by Smith et al. (2020) (26)*

*Figure 2: Implementation Research Logic Model (IRLM) used for the implementation of GLA:D® Switzerland OA*

EBI – Evidence-Based Intervention; PTs – Physiotherapists; MDs – Medical Doctor, IG GLA:D® - Interest Group GLA:D® Switzerland; NCD – Non-Communicable Disease; WHO – World Health Organisation; SLR- Swiss League against Rheumatism; OA – Osteoarthritis

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Figure 1: Implementation Research Logic Model (IRLM) by Smith et al. (2020) (26)

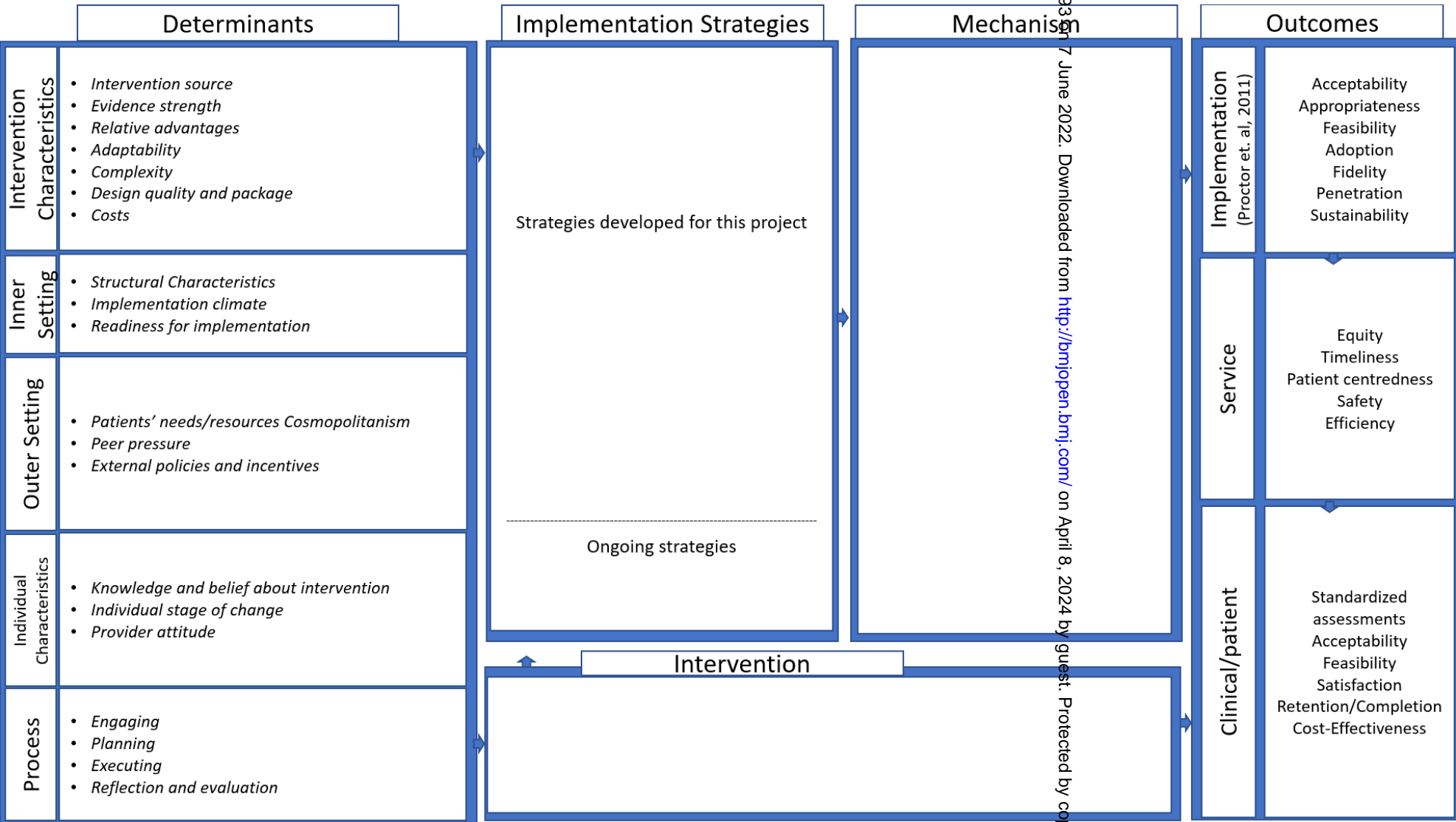
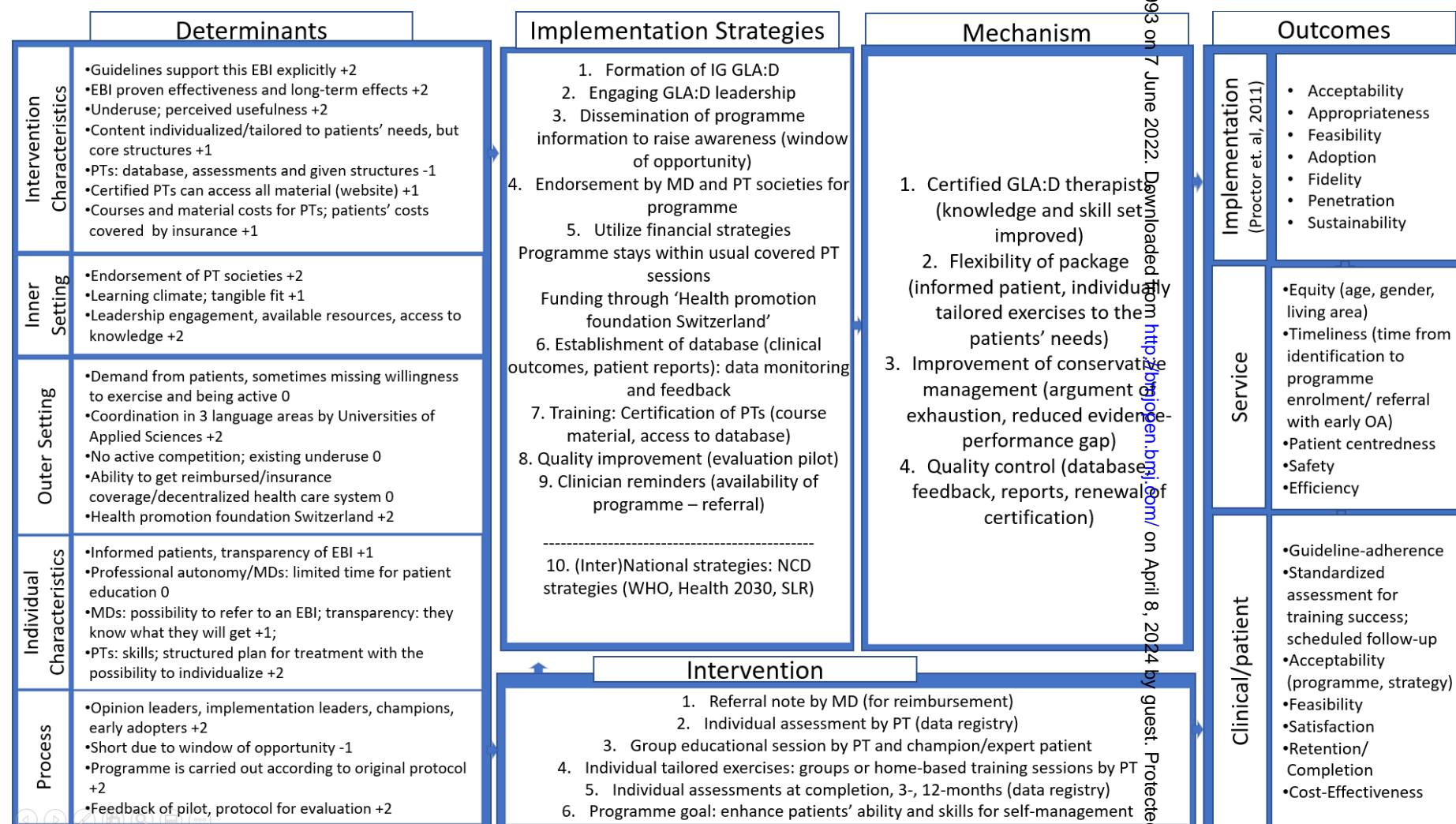


Figure 2: Implementation Research Logic Model (IRLM) used for the implementation of GLA:D® Switzerland OA



EBI – Evidence-Based Intervention; PTs – Physiotherapists; MDs – Medical Doctor, IG GLA:D® - Interest Group GLA:D® Switzerland; NCD – Non-Communicable Disease; WHO – World Health Organisation; SLR- Swiss League against Rheumatism; OA – Osteoarthritis

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Supplement I: Matrix of the influences on the implementation outcomes

	Acceptability	Appropriateness	Feasibility	Adoption	Fidelity	Penetration	Sustainability
<b>Determinants</b>							
Guidelines support this EBI explicitly	X	X					
EBI proven effectiveness and long-term effect	X	X					
Underuse; perceived usefulness	X	X					
Content individualized/tailored to patients' needs, but core structure	X	X	X				
PTs: database, assessments and given structures	X	X	X				
Certified PTs can access all material (website)	X	X	X				
Courses and material costs for PTs; patients' costs covered by insurance	X	X	X				
Endorsement of PT societies	X						
Learning climate, tangible fit	X						
Leadership engagement, available resources, access to knowledge	X						
Demand from patients, sometimes missing willingness to exercise and being active	X	X					
Coordination in 3 language areas by Universities of Applied Sciences	X						
Informed patients, transparency of EBI	X	X					
Professional autonomy/MDs: limited time for patient education	X						
MDs: possibility to refer to an EBI; transparency: they know what they will get	X	X					
PTs: skills; structured plan for treatment with the possibility to individualize	X	x					
<b>Implementation Strategies</b>							
Formation of IG GLA:D							
Dissemination of programme information to raise awareness (window of opportunity)	X	x		X		X	
Endorsement by MD and PT societies for programme	X	x		X			X
Utilize financial strategies	X	x		X		X	X

Programme stays within usual covered PT sessions							
Establishment of database (clinical outcomes, patient reports): data monitoring and feedback							X
Training: Certification of PTs (course material, access to database)	X			X		X	
Quality improvement (evaluation first courses)	X			X		X	
Clinician reminders (availability of programme – referral)	X			X			X
(Inter)National strategies: NCD strategies (WHO, Health 2030, SLR)	X			X		X	X
<b>Mechanism</b>	x			x		X	



Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. BMJ 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. BMJ Open 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.

The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standards refers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			“Implementation strategy” refers to how the intervention was implemented		“Intervention” refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	1	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	2	2	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	3	3/4	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	4	3/4	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).		The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	5	5	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	6	6	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	7	3/4/5/7	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	8	11	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.		The population targeted by the intervention and any eligibility criteria.
Description	9	7/8	A description of the implementation strategy		A description of the intervention
Sub-groups	10	11	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	11	10/11	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets		Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	12	10	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	13	na	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy		Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	14	na	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	15	11/12	Methods of analysis (with reasons for that choice)		
Sub-group analyses	16	11-13	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		

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Results					
Characteristics	17	na	Proportion recruited and characteristics of the recipient population for the implementation strategy		Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	18	na	Primary and other outcome(s) of the implementation strategy		Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	19	na	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	20	na	Resource use, costs, economic outcomes and analysis for the implementation strategy		Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	21	na	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/adaptation	22	na	Fidelity to implementation strategy as planned and adaptation to suit context and preferences		Fidelity to delivering the core components of intervention (where measured)
Contextual changes	23	na	Contextual changes (if any) which may have affected outcomes		
Harms	24	na	All important harms or unintended effects in each group		
Discussion					
Structured discussion	25	15-17	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	26	16	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)		Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	27	17	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		